

A DVD on Orthognathic Surgery: a
randomised controlled trial assessing patients'
knowledge and satisfaction

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by

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Chapter 2. Abstract

Title: BOS Orthognathic DVD: RCT assessing patients' knowledge and satisfaction

Objectives: To compare patients' knowledge of orthognathic treatment and satisfaction with their multi-disciplinary clinic consultation, after receiving information in a standard format versus standard format plus BOS Orthognathic DVD.

Design: Multi-centred, randomised controlled trial.

Setting: Multi-disciplinary orthognathic clinics at four hospitals in Merseyside, UK.

Participants and Methods: 106 participants, age ≥ 16 years, attending their first multi-disciplinary orthognathic clinic, were given information on orthognathic treatment in either the standard format – verbal and written or the standard format plus the BOS Orthognathic DVD.

Primary outcome measures were participants' knowledge of orthognathic treatment and satisfaction with their multi-disciplinary clinic consultation and information provided. Validated knowledge questionnaires were given prior to the multi-disciplinary clinic consultation and 4-6 weeks later. Satisfaction was assessed from participants' response to 16 questions using visual analogue scale. Results of knowledge scores were analysed using ANCOVA at $p < 0.05$, and satisfaction using non-parametric Mann Whitney Wilcoxon test.

Results: Knowledge scores improved from baseline in both groups. Baseline knowledge had a statistically significant effect on participants' follow-up score. No significant difference in knowledge score was found between groups at follow-up once the baseline score had been accounted for. No difference in general satisfaction was found between groups. However, satisfaction with the DVD was significantly less than general satisfaction ($p=0.015$).

Conclusions: There was no difference in participants' knowledge of orthognathic treatment or satisfaction when given information in the standard format or standard format plus the BOS Orthognathic DVD.

Keywords: Consent, Orthognathic treatment; Patient information, knowledge; patient satisfaction.

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Chapter 4. Introduction

A significant number of patients undergo multi-disciplinary orthognathic treatment (MDT) in order to correct their dentofacial disharmony (Moles and Cunningham, 2009). It can be a long, complex treatment process with associated risks that may result in significant morbidity (Cunningham and Johal, 2015).

Before starting any treatment for a patient, it is both a legal and ethical obligation to obtain valid consent (Department of Health, 2009). In order to do this clinicians must impart information to the patient about their treatment options, associated risks and benefits, alternatives to treatment and what may happen if treatment is not carried out. The GDC also states that:

“You should give patients the information they want and need, in a way they can use, so that they are able to make informed decisions about their care.”
(GDC, 2013).

Common law dictates that a patient has a right to information. Patients need to be adequately informed to allow them to make their decision regarding the most appropriate treatment for them. Without the necessary information, in a form that they can understand and the ability of the patient to retain the information, their consent may not be valid. Better information about an elective procedure, such as orthognathic surgery is also a key health policy objective.

Treatment involving a combination of orthodontic and orthognathic surgery for correction of dentofacial discrepancies involves complex multidisciplinary

care involving orthodontists, maxillofacial surgeons, psychiatrists, and many more health professionals. The benefits of this treatment can include an improvement in self-esteem and quality of life. However, there are associated risks with this treatment that may result in significant morbidity or even mortality. It is therefore necessary for a patient to understand what their treatment options are and the risks and benefits of each. Only then can patients be sure that they have chosen the correct and most appropriate treatment.

It is necessary to ensure that the information given is retained by the patient long enough for them to come to a decision about whether to proceed with treatment or not. There are many different methods for provision of information. Although verbal communication is the most common method of communicating with patients, it seems that only 20% of this information is retained (Gauld, 1981a). Visual aids, such as information leaflets, and more recently CDs and DVDs are used in medicine and have been shown to improve patients' ability to retain information (Gauld, 1981a). However, these aids have not been used as extensively in the field of Dentistry. The internet has certainly increased the amount of information available to patients but there is little control and variable quality of information the patients are exposed to online (Brooks et al., 2014).

The British Orthodontic Society (BOS), in collaboration with some orthodontic and maxillofacial consultants, developed and produced a DVD entitled 'A Patient Guide to Orthognathic Surgery' (BDJ 2003) for patients requiring multi-disciplinary orthognathic treatment to correct their malocclusion and

underlying skeletal discrepancy. In a recent study looking into the perspective of patients referred to hospital for orthognathic treatment it was concluded that better information should be provided by the respective orthognathic teams to help some patients with their decision-making as 46% of patients were unhappy with the information provided (Stirling et al., 2007). The BOS Orthognathic DVD has been shown to be a valuable and trusted resource with respect to patient decision making (Flett et al., 2014). However, at present, it is not known whether this DVD will help improve patients' knowledge of orthognathic surgery and whether this leads to an improvement in their satisfaction.(Forssell et al.,1998).

With this in mind, this study was designed as a multi-centre randomised controlled to determine and compare patients' knowledge of orthognathic treatment, and satisfaction with their MDT clinic consultation and information provided, after receiving information in a standard format (verbal and written) alone versus standard and DVD format

Chapter 5. Background and review of literature

5.1 Aetiology of dentofacial deformity

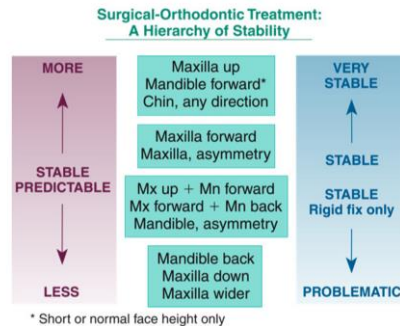
Dentofacial deformity is essentially a developmental problem which may be due to a single causative factor or more commonly, a multifactorial synergistic effect of genetic and environmental influences on growth and development of the dentofacial complex. The inheritability of different malocclusions has been widely demonstrated in a number of familial and twin studies. Horowitz et al. (1960) conducted a study on like-sexed adult twins and demonstrated, using linear cephalometric measurements, highly significant hereditary variations in anterior cranial base, mandibular body length, total face height, and lower face height (Horowitz et al., 1960). Hunter (1965) confirmed a stronger genetic effect on variability of vertical measurements compared with measurements in the anteroposterior. Watnick (1972) conducted a similar twin study and noted differences in the modes of control – environmental and genetic – within the same bone at different sites. Such findings were echoed in other cephalometric twin studies (Lundström, 1948, Kraus et al., 1959) suggesting that whilst genetics appears to dictate the skeletal form and size, environmental factors also contribute to the facial and dental morphology. There are a number of familial studies of heritability of the dentofacial phenotypes. Harris' (Harris, 1975, Harris and Smith, 1982) work demonstrated that, in Class II patients, the mandibular body is smaller and overall mandibular length reduced compared with Class I individuals. It is important to consider the aetiological

factors when planning such a case as it is likely to affect the long term stability of the results.

5.2 Orthognathic treatment

Multi-disciplinary orthognathic treatment, involving orthodontic and maxillofacial surgery is used to treat a wide range of dentofacial discrepancies that are beyond the scope of orthodontics alone. There is often a significant discrepancy in the position and/or size of the maxilla or mandible, or both. The first surgical procedure to correct dentofacial deformity was a mandibular procedure, described as Hüllihen's procedure, in 1849 (Steinhauser et al., 1996). Since this time, surgical procedures have progressed with the first sagittal split osteotomy being described in 1957 (Trauner and Obwegeser, 1957) and the first Le Fort I osteotomies being carried out in the late sixties and seventies (Obwegeser, 1969, Bell et al., 1977). Further to this, advances in general anaesthesia, rigid fixation methods and imaging techniques have allowed bimaxillary surgery to evolve to give the predictable and stable results it gives today (Proffit et al., 2007). The University of North Carolina studies followed up almost 1500 patients that had surgery, for a minimum of one year (1475 patients) up to five years (507 patients) post-operatively, and identified a hierarchy of stability in the immediate twelve month post-surgical period, influenced primarily by amount and direction of jaw movement.

Figure 5.1: Surgical Orthodontic Treatment: A Hierarchy of Stability



Stability continues to be a key issue that needs to be discussed with the patient during the consent process, with regards to the potential for relapse for their malocclusion and surgical procedure.

Orthognathic treatment aims to correct both functional and aesthetic problems related to dentofacial deformity. Such problems are commonly reported by patients as the motivation for orthognathic treatment (Hunt and Cunningham, 1997, Forssell et al., 1998, Stirling et al., 2007, Proothi et al., 2010,). Functional problems include difficulty chewing or achieving an adequate bite, as well as the potential risk to dental and general health, and these are the main reasons cited by patients as their motivation for seeking orthognathic treatment (Laufer et al., 1976, Hunt and Cunningham, 1997, Forssell et al., 1998, Baig, 2004, Stirling et al., 2007, Proothi et al., 2010,). In fact, Proothi et al. found the primary motivating factor was the patients' bite (Proothi et al., 2010), and these findings were echoed in a Scandinavian study which found functional concerns of greater importance than facial concerns (Forssell et al., 1998). Another study, comparing orthodontic only and orthognathic patients, found that the orthodontics only reported fewer functional and temporomandibular joint problems than the surgery group

(Mihalik et al., 2003). Other reasons patients seek treatment include speech problems and temporomandibular joint dysfunction, however; there is little high quality evidence to support the use of orthognathic treatment for such problems. It is therefore important to educate potential patients what problems can be corrected with orthognathic treatment and manage their expectations accordingly.

The negative effects of dentofacial deformity on patients' quality of life and psychosocial well-being have been demonstrated in the literature (Cunningham et al., 1996, Lee et al., 2007, Rusanen et al., 2010, Alanko et al., 2010, Ryan et al., 2012). These feelings can often be deep-rooted resulting from early childhood interactions, but can continue to impact many aspects of patients' adult lives affecting both work and social situations. Another motivation for treatment that patients cited is to improve the psychosocial impact of a dentofacial deformity rather than the physical or functional symptoms themselves (Kiyak, 1991). A recent cross-sectional study by Stirling et al. (2007) looked at the qualitative findings from a structured interview and noted that patients were aware of how their abnormal dentofacial appearance affected their behaviour and self-esteem, and how such effects impacted on their life and their feelings about "difference". It is therefore apparent why patients seek to correct their dentofacial appearance in order to improve their psychosocial wellbeing and quality of life. The World Health Organisation's definition highlights how important quality of life is as an outcome measure in any medical or surgical intervention, and that "health is a state of complete physical, mental and

social well-being”(WHO, 1948). It has been demonstrated that patients expect psychosocial benefits as a result of their orthognathic treatment including improved self-confidence, body-image and better interpersonal relationships as a result of improved social interactions (Rivera et al., 2000). Cunningham et al. (2002) conducted a multi-centred, prospective, longitudinal study of 65 patients who underwent MDT orthognathic treatment demonstrated significant gain in oral health-related quality of life, in pre- and post-operative phases of treatment. They demonstrated considerable improvement in the post-operative phase in three main domains: social aspects, dentofacial aesthetics and masticatory function

Clinical research into quality of life outcome measures is becoming increasingly important. Rustemeyer and Gregersen (2012).carried out a prospective study (n=50) to assess the changes of Quality of Life (QoL) in patients undergoing bimaxillary procedures for the correction of dentofacial deformities. They used OHIP-14 questionnaire with three additional questions specifically relating to orthognathic surgery. They found that psychological factors and aesthetics had a strong influence on quality of life. If there was an improvement in facial aesthetics following surgery, the patients perceived their benefit to be high, and less concerned by functional problems.

Managing patients' expectations is key, and this has been shown to be related to their satisfaction with treatment (Chen et al., 2002). This is especially true as studies have shown that patients can experience a period of disappointment or dissatisfaction when their postsurgical outcomes are

different to their presurgical expectations. Chen et al. (2002) carried out a year-long longitudinal study and demonstrated patients who had realistic expectations were more satisfied in the long term, and found this significant at 3, 6 and 12 months after surgery. They also found that patients with more severe defects were more likely to be satisfied as they had more realistic expectations of what aesthetic and functional improvements could readily be achieved through treatment (Chen et al., 2002).

Orthodontists play a vital role at the initial multidisciplinary consultation appointment and it is important to recognise patients' concerns if they are to manage their expectations appropriately. There are also particular patients whose concerns may be unrealistic due to suffering from a condition such as body dysmorphic disorder, and these patients are likely to be dissatisfied with their outcome regardless of the quality of the treatment provided (Cunningham, 1998). Ensuring patients have sufficient information about orthognathic surgery and carrying out careful interviews may help identify whether patients' responses are out with what would be expected in a normal situation. Such patients can then be provided with the necessary care and support. It is important to ensure that patients have access to appropriate information regarding their treatment, risks and benefits so that they have realistic expectations regarding what can be achieved with treatment. It has been shown that patients with unrealistic expectations of their treatment are more likely to be dissatisfied with the outcome of any care they receive (Cunningham et al., 1996, Chen et al., 2002).

A significant number of patients undergo multi-disciplinary orthognathic treatment (MDT) in order to correct their dentofacial disharmony (Moles and Cunningham, 2009). It can improve aesthetics, function and may have psychosocial benefits. Psychosocial issues related to self-esteem and sociability should be assessed during the diagnosis and treatment planning process to ensure the treatment plan addresses aesthetic functional concerns and the patients' psychological factor. Evidence regarding the psychosocial benefits is limited due to the methodology of research studies due to their retrospective nature and use of questionnaires that had not been validated (Hunt et al., 2001). Although, studies have shown an improvement in patient appearance, self-confidence (Hillerström et al., 1971, Rittersma et al., 1980, Heldt et al., 1982, , Hoppenreijds et al., 1999,), overall mood status and ability to mix socially (Cunningham et al., 1996).

The average treatment time for this treatment is approximately two to three years and includes pre-surgical orthodontic alignment, levelling and coordination of the arches, followed by the surgery and a post-surgical orthodontic phase to detail the final functional occlusion. It is important that patients are well informed of what their treatment will involve especially as the pre surgical orthodontic treatment requires dental decompensation which will often worsen the patients' dentofacial appearance in order to allow for the best skeletal correction and greatest possible stability following surgery. It can be a long, complex treatment process with associated risks that may result in significant morbidity (Cunningham and Johal, 2015) and even mortality (Lanigan, 1988, Van de Perre et al., 1996). Risks can relate to the

pre-surgical orthodontic treatment, the surgical procedure itself or the general anaesthetic involved. Common risks specifically related to the surgical procedure include: pain, swelling, bruising, haemorrhage and infection. Further to this, there is risk of damage to the inferior dental nerve, with incidences of nerve damage apparent during BSSO surgery has been reported to vary from 1.3% to 18% (Al-Bishri et al., 2004). Such damage can result in a permanent or temporary sensory deficit leading to temporary or permanent numbness or paraesthesia affecting the lower lip, chin, teeth, and gingiva. Postoperative paraesthesia or numbness in the lower lip and chin region have been reported to occur in 9–85% of operated sides (Westermarck et al., 1998). This variation in the documented prevalence suggests that neurosensory disturbances after orthognathic surgery are difficult to assess due to differences in standardising clinical assessments and reporting of outcomes. Following judgement in the Montgomery v Lanarkshire Health Board clinicians “must now ensure that patients are aware of any “material risks” involved in a proposed treatment, and of reasonable alternatives (MPS, 2015). Orthodontists play an important role in the initial counselling of patients who are considering a MDT orthognathic treatment approach. It is key that the orthodontist recognises the patients’ specific concerns relating to their treatment and provide information to help the patient come to a decision and give informed consent to the best treatment option for them.

5.3 Communication and patient information

Communication is a key part of any consultation process in the healthcare setting, not only to diagnose and treat the clinical problem, but also to give patients a clear understanding of their condition and the risks and benefits of their treatment options. Clear and effective communication allows health professionals to develop a rapport with patients thus contributing to therapeutic outcomes and allowing patients to make informed decisions in partnership with the people providing their care so that a decision can be made that respects the patients' autonomy (Edwards and Elwyn, 2009). The General Dental Council 'Standards for the Dental team' states that dental professionals need to communicate effectively with their patients:

"Standard 2.3

You must give patients the information they need, in a way they can understand, so that they can make informed decisions" (GDC, 2013).

The initial Orthognathic multidisciplinary consultation is an opportunity for both the orthodontic and maxillofacial consultant to provide the patient with information regarding the nature of their malocclusion, treatment options available and the associated risks and benefits. In the United Kingdom, there is guidance from a number of professional bodies including the Department of Health, Royal College of Surgeons of England and the General Dental Council as to what standards of care are expected from clinicians when obtaining informed consent (Department of Health, 2009; GDC, 2009; RCSE, 2015). The information must be accurate and provided

in a way the patient can understand so that they are equipped to make an informed decision about their care (Stanley et al., 1998).

The consent process must involve a careful dialogue between the patient and their clinician. Patients have the right to autonomy (Grady 2015) and to share in any decisions made about their care – this is essential to providing holistic patient-centred care which is fast becoming the preferred mode of communication in healthcare (Edwards and Elwyn, 2009). A recent orthodontic study suggests that the information should be tailored to each individual patient in order to give them an appropriate amount of information to aid their understanding of the clinical advice (Witt and Bartsch, 1993). Patients' accurate comprehension and retention of the information provided can increase their overall satisfaction and compliance with their care (Ley, 1988, Nanda and Kierl, 1992).

However, it is well documented that a substantial amount of communication with patients is forgotten and/or not understood (Ley, 1972, Witt and Bartsch, 1993). This can lead patients being dissatisfied with the consultation or the amount of information and subsequently they may fail to follow the advice given.

Studies have found that clinicians give different amounts of information depending on the patient's education, income, sex, and age (Waitzkin, 1985). This can be due to clinicians giving more information to some patients than others, for example patients from higher socioeconomic backgrounds, more seriously ill, more educated, and middle-aged generally receive more information from doctors than do their counterparts (Pendleton

and Bochner, 1980). This has been related to the clinician's communicative style which may change the amount of information they give to a particular patient in response to their impression of the patient (Stiles, 1989). This impression can be affected by the patient's personal characteristics or their communicative style (Street, 1991). For example, if a patient is assertive and asks questions relating to their concerns/treatment they are more likely to elicit information from their clinician. It is important to tailor the information to a patient's specific needs and level of understanding, however there is key information about any treatments to which all patients are entitled. It is fundamental to informed consent that the clinician explains and provides information on what the treatment involves, what alternatives exist and the risks and benefits of the different treatment options (GDC, 2013). The General Dental Council 'Standards for the Dental team' states:

"2.2.1 You must listen to patients and communicate effectively with them at a level they can understand. Before treatment starts you must:

- explain the options (including those of delaying treatment or doing nothing) with the risks and benefits of each; and*
- give full information on the treatment you propose and the possible costs."* (GDC, 2013)

Verbal communication is the most common method of communicating with patients, but it seems that only 20% of this information is retained as substantial proportions of conversations are forgotten and/or not understood (Ley, 1988).

Ley produced guidelines for improving verbal doctor-patient communication (Ley, 1988) in order to improve the quality and amount of information that the patient receives, understands and retains. He suggested:

- i. Give advice and instruction as early as possible in the consultation and stress the relative importance of the advice you give.
- ii. Give specific detailed information rather than general comments.
- iii. Use short words and sentences.
- iv. Repeat essential information regarding the diagnosis and treatment.

Previous research has demonstrated that patients have an improved level of satisfaction with their clinician and treatment outcome (Kenny et al., 1998) if they understand information relating to their diagnosis and treatment (Ley, 1988, Garrud et al., 2001, Semple and McGowan, 2002). It has also been shown that patient compliance with any advice given is also related to the satisfaction with the amount of information received during a consultation (Kincey et al., 1975). Improving communication with patients can lead to greater patient satisfaction; better compliance (Kincey et al., 1975) and reduced anxiety (Marteau et al., 1996) which ultimately results in an improved level of satisfaction with their clinician and treatment outcome (Ley, 1988, Garrud et al., 2001, Semple and McGowan, 2002).

Part of valid consent is also that the patient is able to understand and retain the information given to them in order to make an informed decision. This is outlined in the GDC Standards for the Dental team (GDC, 2009):

“2.3.4 You should satisfy yourself that patients have understood the information you have given them, for example by asking questions and summarising the main points of your discussion.”

Recall and retention of information is also related to a number of factors, including social and educational background and the perceived importance of the information being given (Cartwright and O'Brien, 1974). Witt and Bartsch (Witt and Bartsch, 1993) undertook a quasi-experimental study looking at the recall of information provided during an initial orthodontic consultation, after 10 days. Patients were more accurate on topics such as “treatment needs”, side effects or risks (65%), whereas information on diagnosis or orthodontic status was more poorly retained (19.2%). The average result was just more than 30% of information reproduced correctly after 10 days. Patients need enough information so that they can understand the key issues that are likely to influence their willingness (or otherwise) to undergo a particular procedure (DPS 2016). A successful consultation results in the patient’s accurate comprehension and retention of the given information (Witt and Bartsch, 1993) so they can make an informed decision about their treatment.

5.4 Methods of communication

There are many ways in which patients can be informed about their treatment and these include:

- Verbal,
- Patient information leaflet (PIL),

- computer-based material,
- video, or
- DVD
- Web-based information

It has been shown that only 20% of verbal communication is retained (Gauld, 1981b). However, this can be improved by up to 50% if additional visual or written information is provided (Gauld, 1981a). Patient information leaflets (PILs) are therefore used as an additional aid in both general practice and hospital settings as some patients are known to favour written information about their clinical situation, especially if it includes treatment advice. George et al. (1983) found that patients who were given written information on their medications were completely satisfied with their treatment and with the information they had been given, with 66% of patients finding the information useful.

Therefore visual aids, including leaflets and more recently multi-media tools, can be a useful adjunct to provide patients with the necessary information to give informed consent (Kinnersley et al., 2013; Synnot et al., 2014). Such tools have been shown to improve patients' ability to retain information to 50% (Gauld, 1981b), knowledge (Kinnersley et al., 2013). This Cochrane review - 'Interventions to promote informed consent for patients undergoing surgical and other invasive healthcare procedures – included a large number of studies (65) as there was a wide variety of interventions, procedures for which consent was being gained, clinical settings and outcomes being measured. However, only one study assessed all aspects of informed

consent/their primary outcome and this study was at high risk of bias.

Despite the data having substantial heterogeneity, the results were combined. When these results were combined for meta-analyses they found that knowledge improved immediately (up to 24 hours) (SMD 0.53 (95%CI 0.37 to 0.69); I^2 73%, in the short term (1-14 days) (SMD 0.68 (95% CI 0.42 to 0.93; I^2 85%) and the long term (more than 14 days) (SMD 0.78 (95% CI 0.50 to 1.06) I^2 82%). Whilst most of the interventions were written or audio-visual, there were other interventions included so it is difficult to determine which interventions were the most effective due to the heterogeneity and risk of bias in a number of studies. It is important to communicate all the information to the patient in a format that is familiar and acceptable to them so they can engage fully with the information-sharing process. Another recent Cochrane review entitled: 'Decision aids to help people who are facing health treatment or screening decisions' showed that there is high quality evidence that decision aids, compared to usual care, improve people's knowledge regarding options, and reduce their decisional conflict related to feeling uninformed and unclear about their personal values (Stacey et al., 2014). They also found evidence of moderate-quality that decision aids can encourage patients to take a more active role in the decision making process and indicated that patients are better informed, making value-based choices about their care with improved patient-practitioner communication. There are a number of randomised controlled trials that show the effectiveness of different formats used to improve communication of health information between clinicians and patients (Weymiller et al., 2007, Heller et al., 2008, Mullan et al., 2009, Montori et al., 2011, Hess et al., 2012). Studies have also

shown that patients who are well informed are more likely to be satisfied with the care they receive (Williams et al., 2005a).

5.5 Patient information leaflets

Information leaflets are particularly useful if they are written clearly and designed well because they are able to impart a lot of complex, additional information to patients in order to help in their decision-making about the care they are to receive. Leaflets are cheap to produce and can be a useful adjunct as can save patients the embarrassment of asking questions directly of a professional (Ormrod and Robinson, 1994) and increase the retention of clinical information (Gauld, 1981c).

Williams' et al patient centred questionnaire concluded that some orthognathic patients would benefit from being provided with better information about their orthognathic treatment (Williams et al., 2005b). Only 54% of participants could remember being given an information leaflet and around one third had been shown photographs of a patient who had previously undergone orthognathic treatment – over 90% found these helpful. The majority of subjects (93%) felt that they were given adequate information about wearing fixed appliances to enable them to decide whether to proceed with treatment or not. However, participants were less happy with the information that they were given on the duration of treatment and the need to wear retainers. This highlights the importance of informing patients about all aspects of their care.

Stirling et al. carried out a qualitative study and found that whilst 63% of patients had been given written information, about half (46%) were unhappy with some aspects of the information provided including the readability and variability in quality (Stirling et al., 2007). Harwood and Harrison echoed these findings with regards the readability of various Orthodontic patient information leaflets (PILs) and found that they were difficult to read and that only 24–40% of the UK population would be able read them. In addition, none were eligible for the Plain English Campaign's Crystal Mark. The appropriate reading age for written information in the medical setting is 12 years (Thickett and Newton, 2006) as only 54% of the population will understand written material at a reading age of 15 years (Ley and Florio, 1996). Some people also have poor health literacy therefore the language used must be simple with short sentences so it is easy to read and comprehend. If written information is used instead of verbal information, it cannot be assumed that all patients will have read or understood the information provided (Beaver and Luker, 1997) and it is the responsibility of the clinician to ensure the patient has understood what is involved in treatment.

Seehra et al. undertook a cross-sectional assessment of the quality and readability of PILs from two international orthodontic societies – the British Orthodontic Society (BOS) and the American Association of Orthodontists (Seehra et al., 2016). They assessed the quality of each of their leaflets. Quality of information provided was assessed using the DISCERN tool and readability of each leaflet was assessed using the Flesch Reading Ease

instrument, Flesch-Kincaid Grade Level and Simple Measure of Gobbledygook (SMOG) index. PILs produced by the BOS were of higher quality compared to AAO. They found conflicting results on the readability of the leaflets, which is likely due to the reliability of the readability tools which has been previously reported (Charnock et al., 1999, Lewis and Newton, 2006).

The design of health information leaflets has been shown to be poor (Albert and Chadwick, 1992). This has prompted the NHS to produce guidance for producing written patient information (NHS Guidelines, 2010)

- Try to write from the patient's point of view
- Use everyday language
- Use patient-friendly text
- Be relevant
- Make sure information is consistent
- Explain all instructions.
- Give patients the facts about the benefits, risks and side-effects of treatment options or medical interventions.
- Don't confuse people - avoid discussing multiple treatments and conditions in the same leaflet as too much information on different subjects can cause confusion.
- Signpost additional resources.
- Be up to date ensuring that all the information is evidence-based and up-to-date.
- Highlight alternative formats of the information.

5.6 Audio-visual information

Increasing use of audio visual information has been developed in order to overcome some of the deficiencies of paper-based patient information leaflets. They have the advantages of providing a clear visual image with or without an interactive component that can be delivered in the comfort and privacy of a patient's home or 'en masse' to a group of patients. Thompson et al. undertook a questionnaire-based study which compared the effectiveness of written, verbal, and visual (PowerPoint) methods of providing orthodontic information (Thomson et al., 2001a). Short (10-15 minutes) and long-term (8 weeks later) retention of knowledge was assessed of patients and their parents. Overall, only minimal differences were found between the three methods. However, patients' did not seem to cope as well as their parents with verbal information alone, and that parents were more susceptible to verbal instructions. It is difficult to decide on the best type of information for all patients, as every patients needs are different (Yoder, 1994). Clinicians need to be flexible and aware of individual patients information needs in order to use decision aids most effectively to empower patients in shared decision making for those who want it (Bhavnani and Fisher, 2010). It is important to ensure that patients have been able to comprehend the information provided to ensure consent is valid. Holbrook et al. investigated the effects of decision aid format (decision board, decision booklet with audiotape, or interactive computer program) and graphic presentation of data on patients' comprehension and choices of 3 treatments for anticoagulation, and found the decision significantly improved patients'

(96%) knowledge regardless of the format or graphic representation of the data (Holbrook et al., 2007). In another study, a CD-ROM with images of breast reduction surgery was shown to improve patients' understanding but not their comprehension of the potential complications of the surgery. Those who watched the CD-ROM were also significantly less anxious (Danino et al., 2005).

Heller et al. (2008) conducted a randomised controlled trial using an interactive digital education aid for breast reconstruction patients. Although both groups showed improvements, the study group was significantly more satisfied than the control group with the method of receiving information. They also tended to have a reduced mean level of anxiety and increased satisfaction with the treatment choice compared with the control group. Audiotaped recordings of clinic consultations have also been used in some settings as a valuable resource. Most studies evaluating audiotapes are from the field of oncology. They have demonstrated the positive effectiveness in:

- Information provision (Hack et al., 2007)
- Patient satisfaction with treatment (Bruera et al., 1999, Ong et al., 2000)
- Reducing anxiety and depression (Hoseini et al., 2013)
- Increasing patient recall (Ong et al., 2000, Hack et al., 2003)
- Helping patients share information about their medical condition in their support network (Ong et al., 2000)

Bowden et al. (2003) found that over ninety percent of patients who had the consultations recorded thought that the service was beneficial to them and/or their family and friends. They recommended that audiotaping clinic consultations become a standard part of the MDT head and neck oncology clinic in order to improve overall quality of patient care (Bowden et al., 2003). However, results are conflicting and this may be due to risk of bias in some of the studies due to methodological flaws and inadequate sample sizes. A study carried out in general practice setting investigating the efficacy of providing patients with an audiotape of their consultation found that it was positively rated by more than half the patients, there were no detectable clinical effects at follow-up (Liddell et al., 2004).

The use of health information in a video format to supplement verbal and written information can benefit a wide range of people, especially those who have difficulty using the standard printed material offered. Videos have the added benefit of offering a visual element which can be especially useful when trying to convey complex information about treatment procedures to patients.

In a prospective, randomized, single-blind trial, that assessed the effectiveness of a preoperative video as a source of additional patient information before ambulatory surgery found that the video group had better recall of information and concluded that the video was a useful adjunct to routine preoperative consultations (Done and Lee, 1998). Another study in Oncology, showing a videotape describing chemotherapy and radiotherapy found patients to be less anxious and depressed than those patients who did not receive the video tape (Thomas et al., 2000). Overall, there was a

significant correlation between satisfaction and reduced treatment-related anxiety and 81% felt the video was helpful. Another study found that looked at patients preference for video cassette recorded information found that eighty nine percent of patients had easy access to a video-cassette player (Thomas et al., 1999). This statistic is likely to be much lower in today's society as technology has advanced. However, it is important to note what patients' access to being able to view any media platform as the idea is that they can be accessed easily for widespread use. In an orthodontic study comparing written, verbal and videotape instructions about oral hygiene for patients with fixed appliances, it was found that showing a videotape improved plaque index scores (Lees and Rock, 2000).

5.7 DVD information

In the past videos have been used to convey patient information, however videos have largely been superseded by the use of DVD's. Much of the quantitative literature demonstrating improved knowledge (Strevel et al., 2007, Ong et al., 2009, Wilhelm et al., 2009, Solberg et al., 2010,) and satisfaction (Pager, 2005, Strevel et al., 2007, Schofield et al., 2008, Solberg et al., 2010,) is from other medical specialties but these have shown increased knowledge in intervention groups given the DVD as the intervention. Strevel et al. (2007) assessed the influence of an educational DVD in oncology patients that were considering participation in a phase 1 clinical drug trial, and found the DVD was a useful tool for increasing patients' knowledge and satisfaction with the decision-making process.

Improving patients' knowledge about their treatment and satisfaction with the information provided may help to reduce drop-out rates and help target care and resources more effectively. This is important in terms of delivering orthognathic care where drop-out rates have been reported to vary from 7 to 28% (O'Brien et al., 2009, Muqbil I, 2011) both citing the most common reason for drop out being satisfaction with the pre-surgical orthodontics, and only having dental concerns at the start of treatment. It is important that during the initial consultation the patient is able to articulate exactly what they seek to correct with treatment so that the clinicians can advise them about the realistic expectations of treatment outcomes and any limitation of treatment.

5.8 Internet based information

More recently, the internet has vastly increased the amount of information available to patients; however there is little control and variable quality of information that patients are exposed to online due to their unregulated and potentially bias nature (Brooks et al., 2014). Diaz et al (2002) conducted a survey based study of 1000 patients from a primary care practice to assess their usage and perceptions of the quality of information on the internet. They had a response rate of 52%. Interestingly in this study they found that 53.5% of the respondents had used the internet for medical information, and nearly 60% of those who did reported that they did not discuss this information with their doctor. Worryingly, a further 11% said they had actually used the internet instead of seeing their doctor.

Brooks et al. (2014) conducted a systematic search of YouTube™ on lumbar discectomy, identifying over 81 videos that had been viewed 2, 722, 964 (range:139-111,891) times, and found 40 with a rating of “poor” or “inadequate” often due to missing information relating to anaesthesia or complications.

A study in the orthodontic literature by Stephens et al. found that patients aged 10 to 16 years old who were considering orthodontic treatment found the main sources of information was, reassuringly, from dentists (84%). Surprisingly few respondents reported to using the internet for information on orthodontic treatment (8%) despite using the internet regularly for other reasons including social networking. The preferred sources of information were talking to an orthodontist (26%) and family members (12%), followed by talking with the general dentist (10%), viewing a DVD (10%), or reading information leaflets (10%). Patients may be concerned about the reliability of information on the internet. However, it is likely that the use of internet as a resource for patient information will continue to increase and it could be utilised as a useful adjunct to a clinic consultation but patient preference for format of information will always be important. It is advised that reliable orthodontic websites should also ensure that they rank highly on search engine listings (Stephens et al., 2013).

The BOS has recently launched a website entitled “yourjawsurgery.com” (BOS, 2016) – the first UK online resource for patients considering orthognathic treatment (BOS, 2016). The website has four clear sections outlining the patient treatment journey with an explanation of the surgery and

patient stories. It also offers access to other useful resources online and has a section for patient feedback on the resource which will allow further development of the resource in line with a patient-centred outcome approach.

5.9 Patient satisfaction

In general, patient satisfaction with orthognathic treatment is high and this has been demonstrated in the literature – with over 90% of patients reporting improvement in function and/or aesthetics willingness and to recommend treatment to a friend (Cheng et al., 1998). Studies have also shown that patients who are better informed about their treatment are more likely to be satisfied with the care they receive (Cunningham et al., 1996, Chen et al., 2002, Williams et al., 2005a). Cunningham et al. (1996) stated that post-operative dissatisfaction was often not related to the technical skill of the surgeon but rather inadequate preparation of patient on what to expect post operatively. Information provided on orthognathic treatment should to include information on both the orthodontic and surgical aspects of treatment. Previous studies of orthognathic patients have focused on their perception of the quality of information that is provided about their surgical treatment (Rittersma et al., 1980, Flanary et al., 1985, Finlay et al., 1995, Cunningham et al., 1996, Broder et al., 2000,). Williams et al. (2005a) found that orthognathic patients' main motivations for undertaking orthognathic treatment were to straighten their teeth, prevent future dental problems and

improve self-confidence. Whilst 94% of patients felt they were well-informed regarding their orthodontics, 36% of patients wore braces for longer than expected and were surprised at the need for retainers. This suggested that some patients would benefit from better information about some aspects of their care during the preoperative counselling. Interestingly, Dowling et al., (1998) assessed factors influencing the treatment time in orthognathic patients and found the median pre-surgical orthodontics duration was 15.4 months. If treatment involved extractions, the pre-surgical and total treatment times were significantly increased. The number of patients treated by the orthodontists had a significant effect on pre-surgical, postsurgical, and total treatment times which were significantly lower when the orthodontist had treated 10 or more patients during the period. A similar study by Luther et al. (2007) concluded that we should advise patients that the pre-operative phase may last 12-24 months as they found median treatment duration for pre-operative treatment was 17 months (range 7-47 months.) They found that the orthodontist appeared to affect this duration, but stated that this would require further investigation.

5.10 DVD on Orthognathic Surgery

The British Orthodontic Society (BOS) in collaboration with a group of orthodontic and maxillofacial consultants produced a DVD entitled 'A Patient Guide to Orthognathic Surgery' for patients considering a multi-disciplinary orthognathic treatment approach to correct their malocclusion and underlying skeletal discrepancy. It provides patients with information on orthognathic

treatment including the “patient journey”, an explanation of the different surgical procedures that may be required. It also includes information from a patients’ perspective, including pre- and post-operative photographs, a video diary and stories from patients who have previously undergone orthognathic treatment. A key finding from the orthodontic literature is that patients are influenced by those around them and the idea of social ‘norms’ when making a decision about treatment rather than solely on the information from professionals on the risks and benefits of treatment (Trulsson et al., 2002). The role of the BOS DVD in the decision making process of patients considering orthognathic treatment was assessed in a recent qualitative study, and concluded that it was a trusted resource and for some users it helped with the decision making process (Flett et al., 2014). Flett et al. conducted in depth interviews with 10 patients, exploring their attitudes and perceptions that influenced decisions about surgery and the qualitative nature highlighted some aspects of the DVD that could be improved upon. The use of multimedia platforms to give patients information is growing; however, it is not yet known whether such tools will help improve patients’ understanding of and their satisfaction with orthognathic treatment.

The DVD was the precursor to the new website based material entitled “Your Jaw Surgery” which is available through the BOS website (BOS, 2016).

5.11 The research question

As previously discussed, the benefits of multi-media visual aids has been clearly demonstrated in medicine (Stacey et al., 2014), however, its use in

orthodontics and dentistry is less well documented (Flett et al., 2014). It is anticipated that the randomised controlled trial design will allow the findings of this research to contribute a high level of evidence where rigorous studies are limited. This study has been designed to assess the difference in participants' knowledge and satisfaction after watching a DVD entitled 'A Patient Guide to Orthognathic Surgery' for patients requiring MDT orthognathic treatment. This research also hopes to address patient-centred outcomes in order to improve the quality of care in these patients.

If the results of this study confirm an increase in knowledge and/or satisfaction compared to standard care, it would then be justifiable to distribute the DVD to patients after their joint clinic consultation.

Study	Participants	Interventions	Comparison	Outcomes	Results	Comments
(Strevel et al., 2007)	n = 49; Cancer patients newly referred to phase I clinic	Educational DVD	Placebo DVD	- Knowledge and satisfaction questionnaires	Intervention group had: - Increased knowledge, - Increased satisfaction	✓ Sample size calculation ✓ Randomisation ✓ Blinding - Small sample - Non-validated questionnaire - DVD viewed in clinic - Short term
(Nozaki et al., 2007)	n = 47; Patients with unerupted cerebral aneurysms at neurosurgery consultation	Educational DVD	Pre- vs post-DVD questionnaires vs followup	Knowledge and satisfaction questionnaire at: • Before watching DVD • After watching DVD • At followup	- DVD resulted in increase in patient knowledge and satisfaction	- Case series - ?Adequate power - No control group - Pre/post design - ?Validated questionnaires

(Schofield et al., 2008)	n = 100; Patients due to have first ever chemotherapy	Usual care + DVD Usual care only	Historical control	<ul style="list-style-type: none"> - Disease variables - Satisfaction* - Anxiety/depression - Self-efficacy* - Perceived needs* 	<ul style="list-style-type: none"> - Self perceived curative more satisfied with DVD group vs usual care, - And DVD group more confident seeking support - Self-perceived palliative patient more satisfied in DVD group 	✓ Prospective cohort study <ul style="list-style-type: none"> - No randomisation - Selection bias - Multiple testing - Post hoc power analysis - Low response rate
(Wilhelm et al., 2009)	n = 259; Patients undergoing cholecystectomy	- Educational DVD + consultation	- Control – consultation only	- Knowledge questionnaire	Increased knowledge with DVD group	✓ Prospective RCT <ul style="list-style-type: none"> - ?Allocation concealment - Non-validated questionnaire - Higher baseline knowledge in DVD, ?if controlled for this - Per protocol analysis - Loss to follow-up
(Solberg et al., 2010)	n = 300; Females facing a treatment decision for fibroids over 13 months	- DVD + booklet + Worksheet +Nurse coach	- Control (pamphlet)	<ul style="list-style-type: none"> - Satisfaction questionnaire - Knowledge questionnaire 	Increased satisfaction and knowledge in intervention group	<ul style="list-style-type: none"> - ?Selection bias - Group randomisation - ?Baseline scores - Combined interventions

(Powell-Jackson et al., 2010)	n = 237; Women requesting termination of their pregnancy and staff	- DVD	- Control (before watching DVD)	- Knowledge and - Satisfaction scores	- Increased patient reported knowledge - Increased satisfaction	- Selection bias due to recruitment issues - No randomisation - No blinding - No objective measure for knowledge – patient reported outcome ✓ - Loss to follow up
(Ryan et al., 2012)	- 4 trials (3 randomised and 1 quasi-randomised control trials)	- Audiovisual information alone Or - Audiovisual information in conjunction with standard format)	- Standard forms of information provision (written/oral alone)	- Satisfaction; - Understanding; - Recall of information; - Level of anxiety - Their decision to participate	- Mixed evidence as to whether audiovisual interventions enhance knowledge	✓ Systematic review ✓ Good methodology ✓ Good selection criteria - Small number of studies met inclusion criteria - No meta-analysis due to heterogeneity - Conflicting results

(Thomson et al., 2001b)	n = 84; patients and parents attending orthodontic new patient clinics	- Written information leaflet - Visual information, Power point	- Verbal information,	- Questionnaire to assess: <ul style="list-style-type: none"> • Short term (10 - 15 minutes) and • Long term (8 weeks) retention of information 	- Patients did significantly better with written information - Parents did better than child with verbal in long and short term	- Convenience sample - No sample size calculation - Alternate allocation - Loss to follow up (25%)
(Flett et al., 2014)	n = 10; Qualitative study	- BOS Orthognathic DVD		- Semi structured interviews - Topic guide: patient stories; use of images; nature of DVD; usefulness in decision making process	- DVD seen as trusted resource - some ideas for improvements	✓ Prospective cross-sectional ✓ Purposive sampling ✓ Interviews in patients home - external validity

Table 5.1: Studies included in literature review

Chapter 6. Aims and hypotheses

6.1 Aims

The purpose of this study was to compare patients' knowledge of orthognathic treatment, and satisfaction with their MDT clinic consultation and information provided, after receiving information in a standard format (verbal and written) alone versus standard and DVD format.

6.2 Objectives

1. To determine participants' knowledge of orthognathic surgery, and satisfaction with their joint clinic consultation and information provided, when information about orthognathic surgery is provided in a standard format (verbal and written) alone versus standard and DVD format.
2. To compare participants':
 - Knowledge of orthognathic surgery;
 - Satisfaction with their MDT clinic consultation and information provided

6.3 Null hypotheses

We tested the null-hypotheses that there is no difference in participants'

1. knowledge of orthognathic treatment;
2. satisfaction with their MDT clinic consultation and information provided

whether they were provided with information in a standard format alone or standard and DVD format versus the alternate hypothesis of a difference.

Chapter 7. Participants and methods

7.1 Trial design

A 2-arm, parallel group randomised controlled trial with a 1:1 allocation ratio.

7.2 Participants, eligibility criteria and settings

Participants were recruited from patients attending the multi-disciplinary orthognathic clinics at Arrowe Park Hospital, Countess of Chester Hospital, Halton General Hospital and Liverpool University Dental Hospital. The trial was approved by Liverpool Research Ethics Committee for Liverpool University Dental Hospital and Halton General Hospital and site specific approval from Local Research Ethics Committees at Arrowe Park Hospital and Countess of Chester Hospital. The REC reference number for the study was 08/H1005/75. The trial was carried out in compliance with the principles of Good Clinical Practice (MHRA, 2014) and in accordance with the Department of Health Research Governance Framework (HRA, 2005).

7.3 Eligibility criteria

Inclusion criteria included patients who were:

- aged 16 and over,
- attending their first multi-disciplinary orthognathic clinic having previously been seen at an orthodontic or oral and maxillofacial surgery new patient clinic following referral to the hospital.

Exclusion criteria included patients who:

1. had previously received orthognathic treatment,
2. were younger than 16 years, and
3. with congenital craniofacial anomalies or acquired defects.

7.4 Interventions

All participants were given information on orthognathic treatment at their MDT clinic in the standard format. This involved a general discussion with the orthodontic and maxillofacial surgery consultants outlining the possible treatment options, associated risks/benefits and alternatives to treatment. This was supplemented with a Trust approved patient information leaflet (PIL) on orthognathic treatment to read at home. After the MDT clinic consultation, participants allocated to the experimental group were also guided through the BOS DVD 'A Patient Guide to Orthognathic Surgery' by a trained clinician or research assistant, and given a copy to take home and watch. All participants were given a follow-up appointment 4 to 6 weeks later.

7.5 Outcomes

The primary outcome measures in this study were the patients' knowledge of orthognathic treatment and their satisfaction with their MDT clinic consultation and the information provided.

7.5.1 Knowledge

A questionnaire was devised to collect data on knowledge and was shown, in the pilot study, to be a valid and reliable tool for assessing patient knowledge

on orthognathic surgery (Pye et al., 2010). The questions were derived from the standard PIL with which all participants had been provided. These questions were randomly selected to be written as either true or false statements by computer randomisation. A dichotomous forced response system was employed for assessing knowledge and respondents answered true, false or unsure to each question. Answers were indicated in a tick box. A score of 1 was given for a correct response and a score of 0 was given for an incorrect or unknown response. The unsure option was provided to minimise the potential for participants randomly guessing the answer. This would have subsequently resulted in a high measurement error and therefore the knowledge questionnaire would have had low reliability. In addition, the unsure option bridges the difference between what the patient knows and what he or she scores.

The questionnaire was assessed in the pilot study for validity, reliability and acceptability to ensure the measurement tool was free from any bias and accurate for assessing patients' knowledge (Pye et al., 2010). This ensured that any inferences made, based on the questionnaire scores recorded, were valid.

The validated and reliable knowledge questionnaires were given to the experimental and control groups once consent had been obtained and prior to their first MDT clinic consultation (baseline, T_0). Participants in both groups then completed the same questionnaires again, after the review appointment, 4-6 weeks later (follow-up; T_1).

Please see Appendix 1 for the knowledge questionnaire

7.5.2 Satisfaction

The participants' satisfaction with their MDT clinic consultation and information provided was assessed using a patient satisfaction questionnaire. The questionnaire was derived from a questionnaire used in a previous study assessing the impact of an information leaflet on patient satisfaction (Brindley, 2005). Satisfaction was assessed using a visual analogue scale (VAS). This scale consisted of a 10cm visual analogue scale (VAS) tethered, at each end by, a vertical line, one labelled 'Strongly agree' and other labelled 'Strongly disagree'. The participants were asked to mark an 'X' on the horizontal line at a point that corresponded to their level of satisfaction. The distance from the end points were scored and analysed.

The satisfaction was completed at the review appointment (T₁) only, which was 4-6 weeks after the first MDT clinic consultation.

Please see Appendix 2 for the satisfaction questionnaire.

There were no outcome changes after commencement of the trial.

7.6 Sample size

Using data from a similar study undertaken within the department (Brindley, 2005) and assuming normal distribution of data with a standard deviation of 3 for the scores in each group, a 2-sided t-test with a 5% significance and 80% power, suggested that 37 participants in each group were needed to detect a difference of 2 points in the knowledge score. However, this was modified in light of the results of the pilot study and to taking account of the anticipated drop-out (Pye et al., 2010). A similar study assessing the effectiveness of

orthodontic/orthognathic treatment care in the United Kingdom found a drop out of 28% of participants who did not complete their treatment and did not have orthognathic treatment (O'Brien et al., 2009). From the pilot study, Pye et al., (2010), the dropout rate was similar to that in the O'Brien study suggesting a minimum of 48 participants were required in each group to give adequate statistical power.

7.7 Consent

Potential participants were given information about the trial before their first multidisciplinary orthognathic appointment. Any questions or concerns were answered by the trial coordinators (GP, EW, LC). Eligible patients were invited to participate in the trial and written informed consent was obtained from patients willing to participate, by a clinician (EW, GP, RG) or research assistant (LC).

Please see Appendix 3 for information leaflets about the trial and Appendix 4 for the consent form.

7.8 Randomisation (sequence generation, allocation concealment, implementation)

Once consent had been obtained, each participant was randomly assigned to the control or experimental group. Sequence generation was by the research supervisor (JEH) who was independent from the recruitment process. Randomisation was carried out in blocks of six and stratified by trial centre. Allocation to experimental or control was typed on cards which were then placed in sealed, opaque, sequentially numbered envelopes held in

each department. A log was kept of the participants' ID and the number of allocated envelope.

7.9 Blinding

The trial was single blinded. Assessment was blind as the data analyst (EW), assessing the questionnaires and measuring the VAS scales, did not know to which group each participant had been assigned until the randomisation code was broken. It was not possible to blind the participants to the intervention, as the interventions were different.

The consultants leading the MDT clinic did not know to which group the participants had been allocated because the recruitment process and allocation was carried out separately after the MDT clinic consultation.

7.10 Data protection

All questionnaires had an ID number to identify them to comply with the Trust's data protection policy. The completed questionnaires and the master sheet, which linked patient details to the ID number, were all stored in a locked filing cabinet in Eileen Watt's office at Liverpool University Dental Hospital.

7.11 Statistical analyses

Analysis of covariance, adjusting for pre-intervention scores, was used to compare the post-intervention scores between the groups. The scores were checked for normality. They were found to be non-normally distributed so non-parametric tests were used for analysis. Data were analysed on an

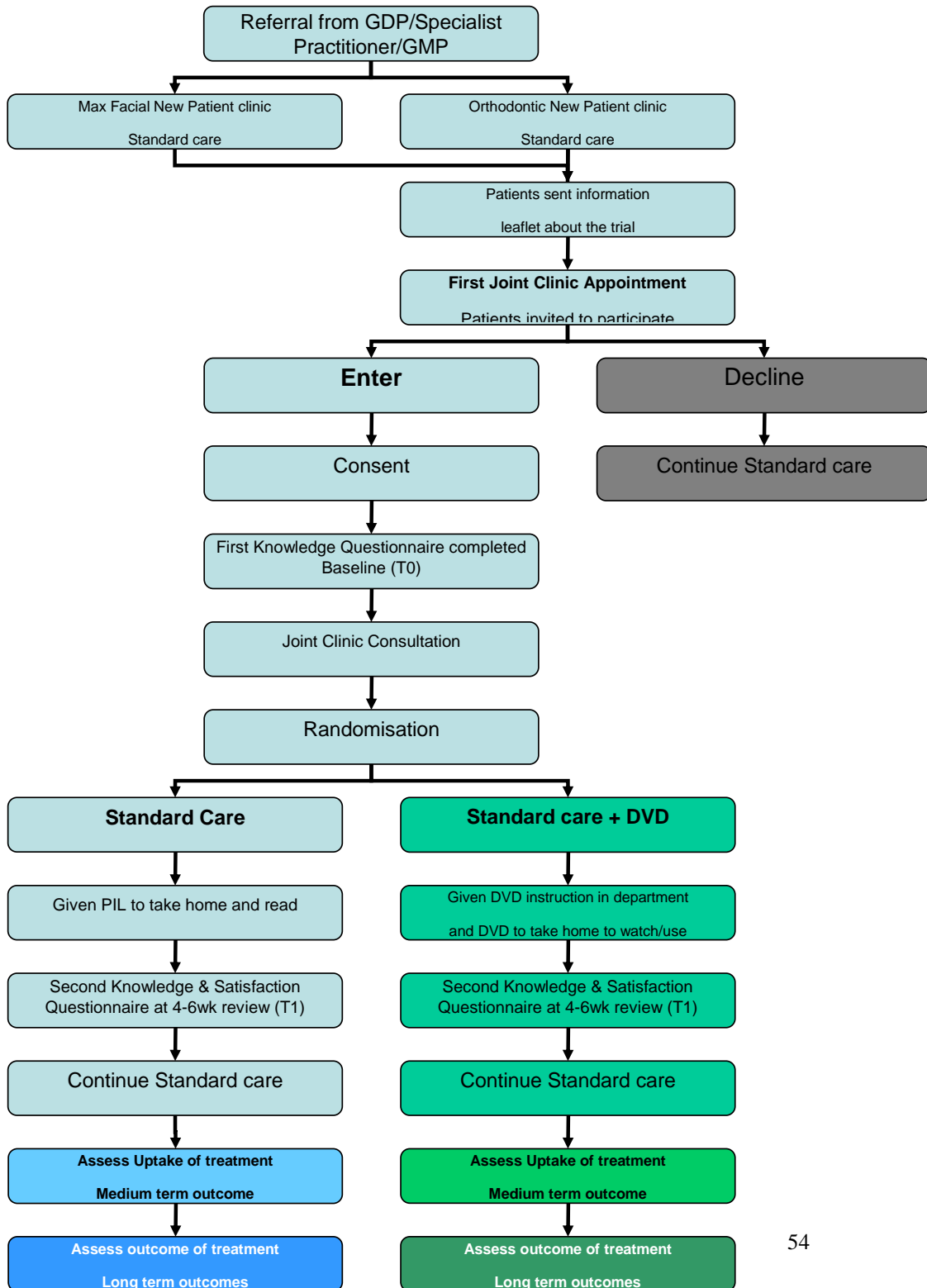
intention to treat basis using SPSS software (version 22.0, SPSS, Chicago, III).

7.12 Dissemination of results

The results of the pilot study and the main study were presented at the 'University Teachers Group' Session at the British Orthodontic Conference in 2010 and 2016 respectively. Two papers outlining the results of pilot and main study will be submitted for publication in the Journal of Orthodontics.

Orthodontic departments within the Merseyside region will also be informed of the outcomes of the study and whether or not viewing a DVD entitled "A Patient Guide to Orthognathic Surgery" by patients requiring MDT orthodontic and orthognathic treatment makes a difference in patients' knowledge and satisfaction.

Figure 7.1: Method of study flow chart



Chapter 8. Results

8.1 Recruitment

One hundred and thirty patients were assessed for eligibility to participate in the study - five were not eligible, as they were under sixteen years of age and 19 declined to participate in the study. Of these 19, four did not want to see the DVD so therefore did not want to participate; 3 had personal reasons for not wanting to take part in a research study; 2 patients did not have time to participate and for 10 patients, no reason was stated. All patients who declined to participate continued on their clinical treatment pathway as normal. The study therefore included 106 participants.

8.2 Participant flow

One hundred and six patients were enrolled, 54 were allocated to the DVD group (38 females; 16 males) average age, 22.33 years; SD, 7.31(95%CI 20.32, 24.35) and 52 (29 females; 23 males) average age, 24.28 years; SD, 8.79 (95%CI 21.81, 26.73) to the control. However, one patient's data in control group was missing as it had not completed correctly so data was unavailable. All participants received the intervention to which they were allocated, however, four of the participants who received the DVD, chose not to watch it – two felt the DVD would discourage them from treatment, and 2 reported that they had not had time to watch the DVD. Further to this, 13 participants (24.1%) in the DVD group and 6 (11.8%) in the control group were lost to follow-up as they did not return for their review appointment so could not complete the questionnaires at T₁.

Enrolment for the pilot ran from 5th March 2010 – 21st December 2012 and for second cohort of patients to the main study to complete recruitment from 12th May 2014 - 6th August 2015, and the final follow-up was on 3rd September 2015.

Those participants who did not attend their follow-up were sent subsequent appointments as per the hospital protocol, and the follow-up questionnaires were posted to them in stamped address envelopes on two occasions, after which if they did not respond, they were counted as being lost to follow-up. Six (11.8%) were lost to follow-up in the control group and 17 (31.5%) in the DVD group. This difference was statistically significantly different (OR 3.45, 95%CI 1.23, 9.63).

The flow of participants involved in the study is outlined in Figure 8.1.

Figure 8.1: Consort flow diagram

CONSORT
TRANSPARENT REPORTING of TRIALS
CONSORT 2010 Flow Diagram

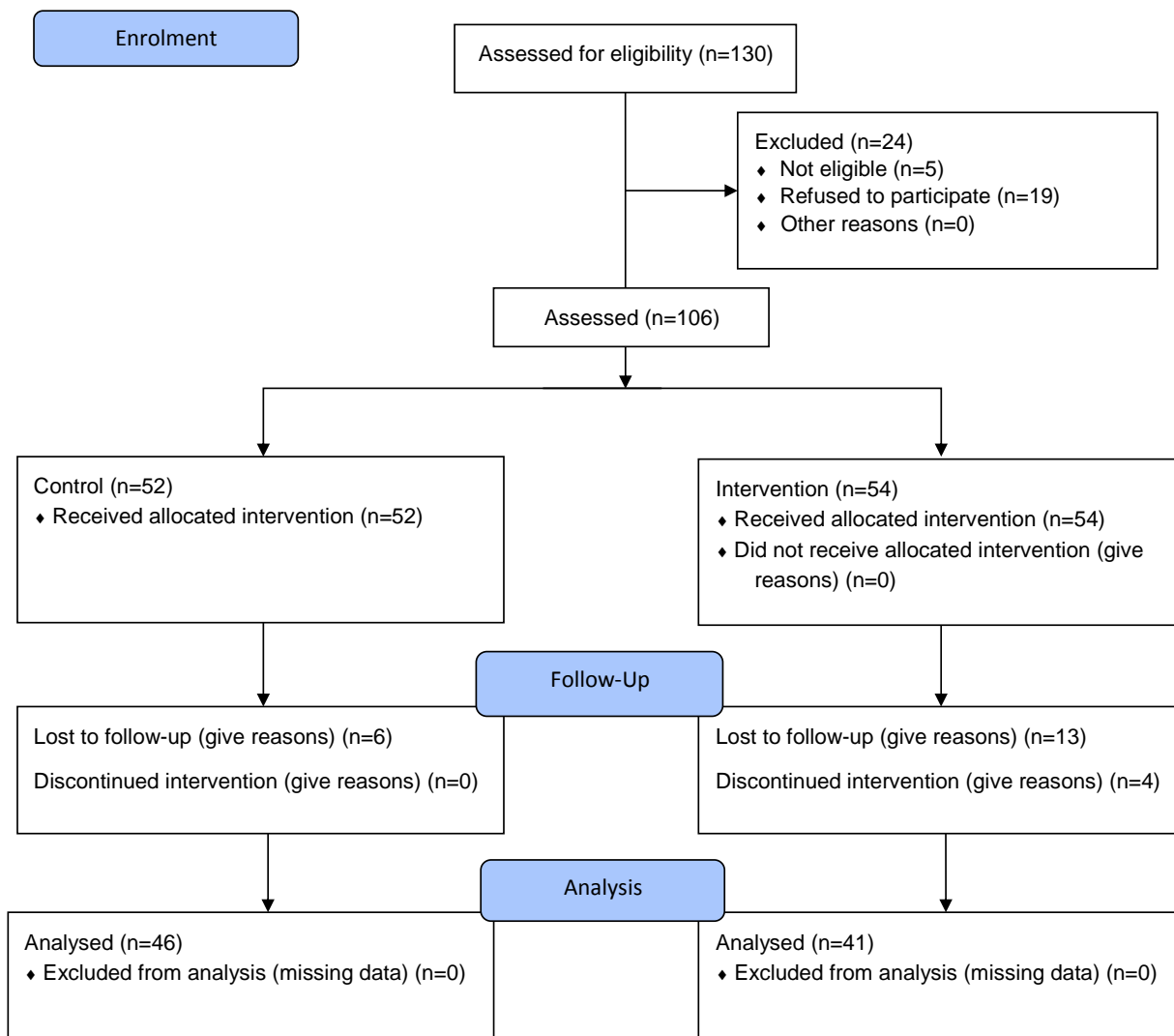


Table 8.1 shows the baseline characteristics of the participants involved in the study, including age, gender and mean total score at baseline. These were similar for all groups at the start of treatment, however it is noted that there was a larger proportion of females in the DVD group compared with the control group, OR 1.95, 95%CI 0.87, 4.36.

Table 8.1: Baseline characteristics of participants

	Number	Age years;			Baseline knowledge score			Gender (Female)	
	N	Mean	Std dev	95% CI	Mean	Std dev	95% CI	N	%
Control Standard Info	52	24.28	8.79	(21.81, 26.75)	15.31	4.90	(13.94, 16.69)	29	56
Experimental DVD	54	22.33	7.31	(20.32, 24.35)	14.26	5.39	(12.78, 15.74)	38	70

8.3 Knowledge

The primary analysis was an intention to treat analysis so included all participants who were randomised (n=106). Baseline and follow-up Knowledge scores were obtained for the Standard Information (Control) and DVD (Experimental) groups. The differences in the scores for knowledge in the standard group and the DVD group were then compared.

8.3.1 Shape and Distribution of Change in Knowledge data

The boxplot Figure 8.2 shows the range of data for the scores in knowledge for the Standard (Control) and DVD (Experimental) groups at Baseline.

Figure 8.2: Box plot showing range of Knowledge scores at baseline

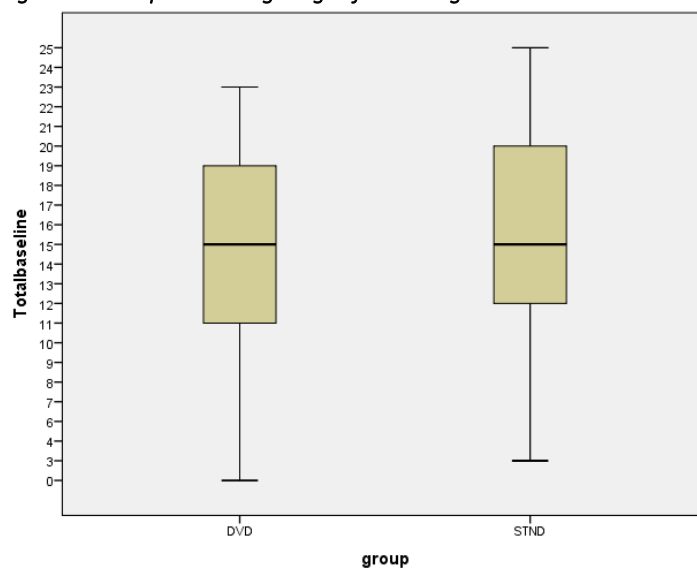


Table 8.2 Mean baseline knowledge scores

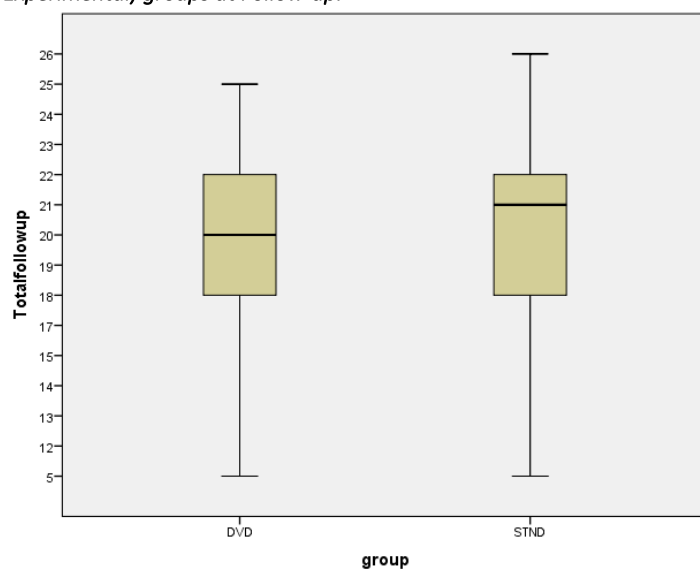
	Number	Baseline knowledge score		
	N	Mean	Std dev	95% CI
Control Standard Info	52	15.31	4.90	13.94, 16.69
Experimental DVD	54	14.26	5.39	12.78, 15.74

It can be seen that the mean scores were similar in both groups with wide overlapping confidence intervals. The lowest and highest scores were lower in the DVD group. It can also be seen that the whiskers of the boxplot are similar in length suggesting the variability of scores between groups was similar.

Total baseline knowledge score had a statistically significant effect on participants' follow-up score, ANCOVA $F(1, 84) = 226.97$, $p < 0.05$ suggesting that follow-up score was influenced by baseline knowledge.

Figure 8.3 shows the range of data for the scores in knowledge for the Standard (Control) and DVD (Experimental) groups at follow-up

Figure 8.3: Boxplot showing Knowledge Score for the Standard (Control) and DVD (Experimental) groups at Follow-up.



The boxplot shows that participants in the Standard (Control) group scored better than those with the DVD (Intervention) group, but that there was greater variation in scores in the Standard (Control) group with wide overlapping confidence intervals.

Table 8.3 Mean follow-up knowledge scores

	Number	Baseline knowledge score		
		Mean	Std dev	95% CI
Control Standard Info	46	20.09	3.83	(18.95, 21.22)
Experimental DVD	41	19.54	3.97	(18.28, 20.79)

The box plot in Figure 8.4 shows the change in knowledge scores for the Standard (Control) group and DVD (Experimental) group.

Figure 8.4: Box plot showing Change in Knowledge scores for the Standard (Control) group and DVD (Experimental) group.

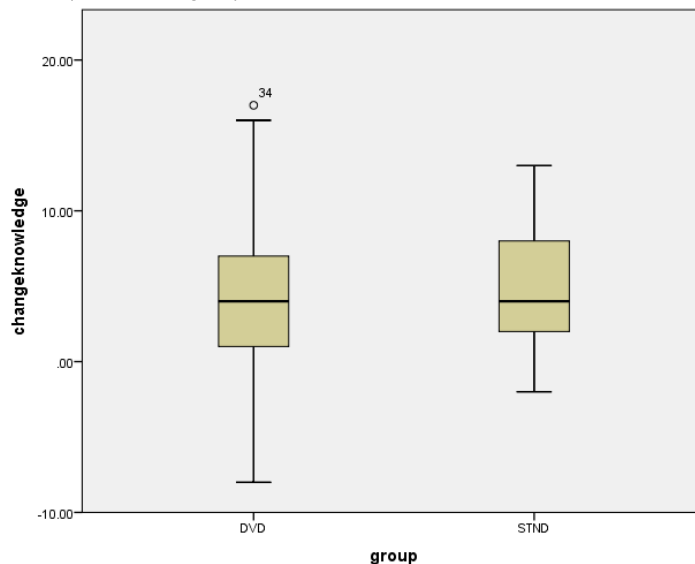
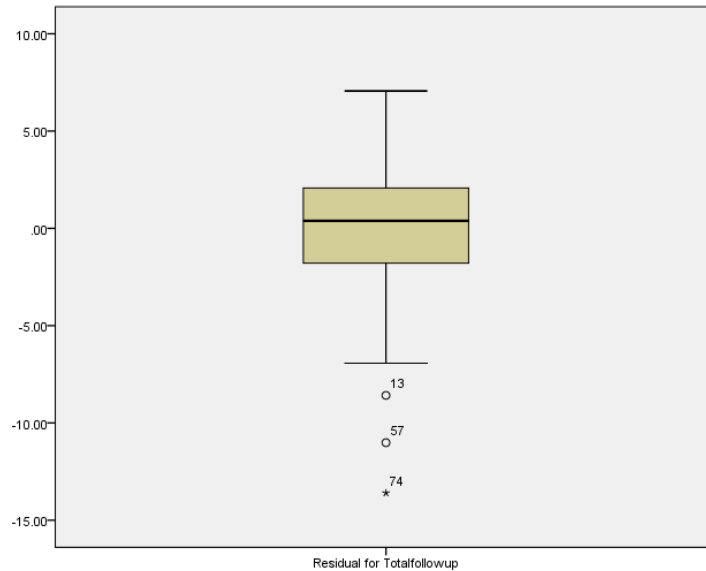


Figure 8.4 shows similar change in knowledge scores for the Standard (Control) and DVD (Experimental) group. The DVD group showed much greater variation in change in knowledge than the Standard (Control) group. There was one outlier in the DVD (Intervention) group.

8.3.2 Normality

ANCOVA tests for normality of the residuals, and they were not found to be normally distributed using the Shapiro – Wilks. The test statistics were 0.940 df 87 ($p=0.001$) which is statically significant suggesting departure from normality.

Figure 8.5: Box plot showing residuals for Total Follow-up score for both the Standard (Control) group and DVD (Experimental) groups.



This box plot demonstrates that there were three outliers with the three lowest values. See section on modified data.

8.3.3 Knowledge scores

Table 8.4 shows the mean knowledge scores for both groups at baseline (T0) and follow-up (T1) and the change in knowledge. See Appendix 7 for descriptive statistics on baseline knowledge and follow-up knowledge.

Table 8.4 Mean knowledge scores

	Number	Baseline knowledge score			Follow-up knowledge score		
	N	Mean	Std dev	95% CI	Mean	Std dev	95% CI
Control Standard Info	46	15.31	4.90	13.94, 16.69	20.09	3.83	(18.95, 21.22)
Experimental DVD	41	14.26	5.39	12.78, 15.74	19.54	3.97	(18.28, 20.79)

	Number	Change in score		
	N	Mean	Std dev	95% CI
Control Standard Info	46	4.80	1.07	(3.59, 6.01)
Experimental DVD	41	4.71	5.56	(2.95, 6.46)

8.3.4 Analysis of covariance

Knowledge scores improved for both groups at T₁. The results of data analysis are found in Table 8.5.

Analysis of COVariance (ANCOVA) was conducted to determine if statistically significant difference between the Standard information and DVD groups total follow-up score, adjusting for the original baseline score. The total knowledge score at baseline significantly predicted the knowledge score at follow-up ($226.97 F(1; 84) = 226.97, p < 0.05$) suggesting that the follow-up knowledge score was influenced by the baseline knowledge score. When the effect of the baseline score was removed, the difference between groups was not significant. There was no statistically significant differences between groups in total follow-up score after controlling for baseline score ($F(1; 84) = 0.27, p = 0.602$). The effect of the covariate, baseline knowledge score was that the baseline knowledge score was significantly associated with the follow-up score ($F(1; 84) = 17.93, p < 0.001$). The differences between the scores were small, with wide confidence intervals. The R^2 value signified that the model only explained 16% of the variation in knowledge gain. As a result, we concluded that neither method of information (DVD or Leaflet) was superior to the other in terms of improving participant's knowledge of orthognathic treatment.

Table 8.5 ANCOVA models for the effects of intervention on follow-up knowledge score

Outcome	Effect of treatment (95% CI)		Overall effect of treatment	R^2	Covariate
Follow-up knowledge score	DVD	Standard Information			
Mean (95%CI)	19.54 (18.28, 20.79)	20.09 (18.95, 21.22)	$F(1, 84) = 0.27$ $p = 0.602$	0.180	Total baseline score

The null hypothesis was therefore accepted and it was concluded that there was no statistically significant difference in knowledge between the Standard information (control) and DVD (Intervention) groups.

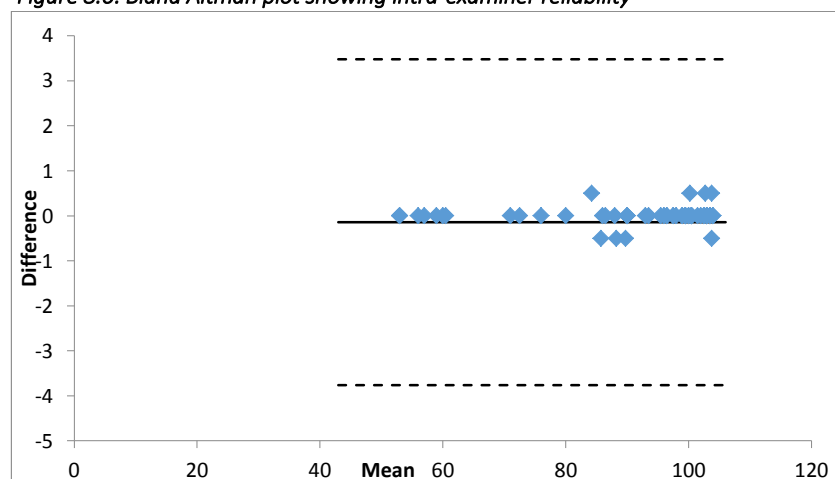
See Appendix 8 for complete data.

8.4 General Satisfaction

8.4.1 Reliability

Intra-operator reliability was assessed for measurement of the VAS scales of the satisfaction questionnaires eight weeks after initial measurement. The analysis was carried out on 10% of the questionnaires selected using a random number generator. The interclass coefficient was 0.993 (95%CI 0.991 – 0.994) was used for the continuous data and indicated almost perfect agreement. This suggested that the method of recording the data and measuring the VAS had a high level of reliability.

Figure 8.6: Bland Altman plot showing intra-examiner reliability



The Bland and Altman plot shows no significant systematic or random error, with a mean difference of -0.14, limits of agreement -3.76 and 3.48.

8.4.2 General satisfaction

Both the standard information (Control) and the DVD (Experimental) groups completed the general satisfaction section of the satisfaction questionnaire (questions 1-13). Both groups had similar scores in general satisfaction however there seemed to be greater variation in the scores of the DVD group as demonstrated by the whiskers on the boxplot.

8.4.3 Shape and distribution of General Satisfaction Data

Figure 8.7: Box plot showing the General Satisfaction scores for the Standard (Control) and DVD (Experimental) groups.

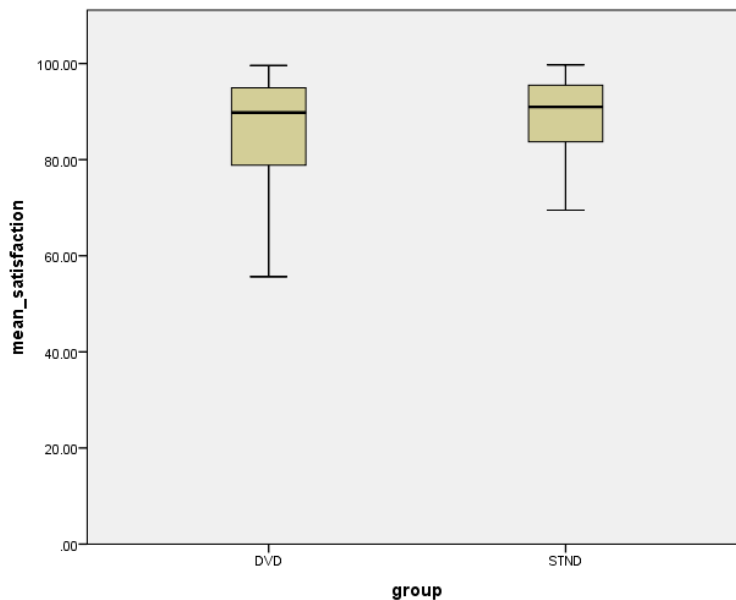
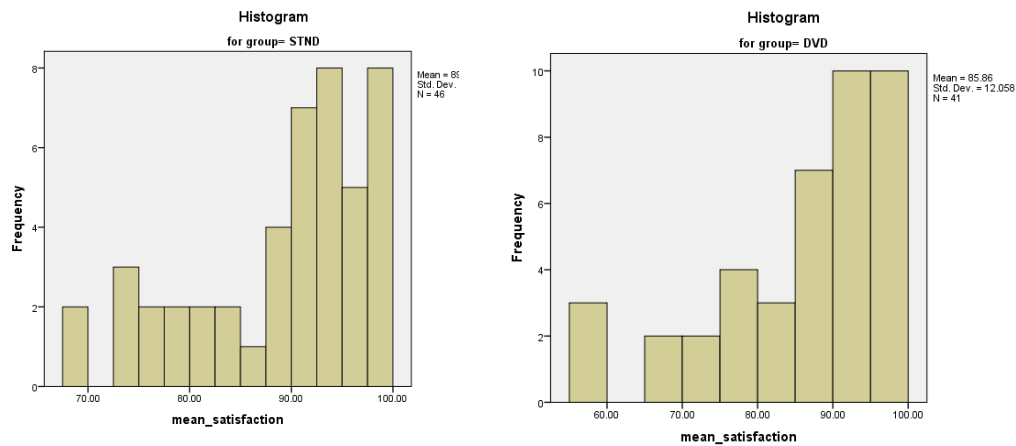


Figure 8.7 shows that both groups had similar scores in general satisfaction and there were no outliers. There was, however, greater variation in the DVD (experimental) group.

8.4.4 Normality

Figure 8.8 Histogram of General Satisfaction scores for a) Standard (Control) and b) DVD (Experimental)



a) Standard (Control) and

b) DVD (Experimental)

The boxplots do not appear to be normally distributed. Shapiro-Wilk test for normality, are statistically significant DVD 0.873; df 41; $p < 0.001$ and Standard 0.903; df 46; $p < 0.001$), suggesting that neither come from a normally distributed dataset, and so non-parametric tests were used.

Table 8.6: Test for normality

Tests of Normality							
	group	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
mean_satisfaction	DVD	0.186	41	0.001	0.873	41	0.000
	Standard	0.161	46	0.004	0.903	46	0.001

8.4.5 General Satisfaction Data

Table 8.7 shows the participants' satisfaction scores for their MDT clinic appointment. The median general satisfaction scores for the Standard information and the DVD groups were 90.97% and 89.78% respectively; the differences in the two groups were not statistically significant (Mann–Whitney $U=821.0$, $n_1=46$ $n_2=41$, $P=0.3$ two-tailed). See Appendix 10.

Table 8.7 General Satisfaction Data

	Group	N	Mean (%)	95% Confidence Interval	Median (%)	Standard deviation	Standard Error Mean	IQR
General Satisfaction	Standard	46	89.13	(86.57, 91.69)	90.97	8.63	1.27	12.54
	DVD	41	85.86	(82.05, 89.66)	89.78	12.06	1.88	17.27
DVD satisfaction	DVD	32	81.52	(76.14, 86.89)	85.23	14.92	2.64	24.00

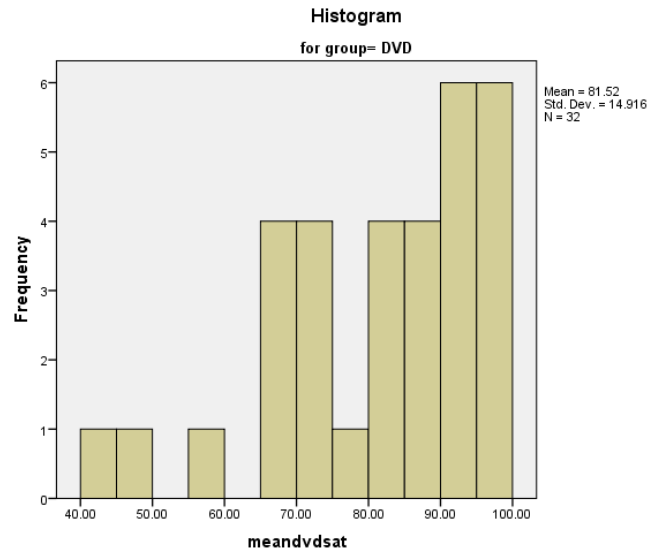
The null hypothesis was therefore accepted and it was concluded that there was no statistically significant difference in participants' general satisfaction with their MDT clinic appointment between the standard information and DVD groups.

8.5 DVD Satisfaction

Those randomized to the DVD group, also answered questions relating to their satisfaction with the DVD. Of the 54 participants in this group, 13 were lost to follow-up as they did not return to the review appointment. 32 participants completed the DVD satisfaction section, 9 participants allocated to the DVD group did not complete this section, and some admitted this was because they had not watched the DVD, although they had been given it.

8.5.1 Normality

Figure 8.8: Histogram of DVD satisfaction scores for DVD (Experimental) group



8.5.2 DVD Satisfaction Scores

Table 8.8 shows the median score for DVD satisfaction was 85.22% (IQR 24) and the median general satisfaction score was 89.78% (IQR 17.27).

There was a significant difference in general and DVD satisfaction scores implying that participants were less satisfied with the DVD than the general information/joint clinic appointment ($p=0.015$).

Table 8.8: General Satisfaction and DVD Satisfaction scores for the DVD (experimental) group

Group	N	Mean (%)	95% Confidence Interval	Median (%)	Standard deviation	Standard Error Mean	IQR
DVD satisfaction	32	81.52	(76.14, 86.89)	85.23	14.91	2.64	24
General satisfaction	41	85.86	(82.05, 89.66)	89.78	12.06	1.88	17.27

8.5.3 Correlation of knowledge and satisfaction.

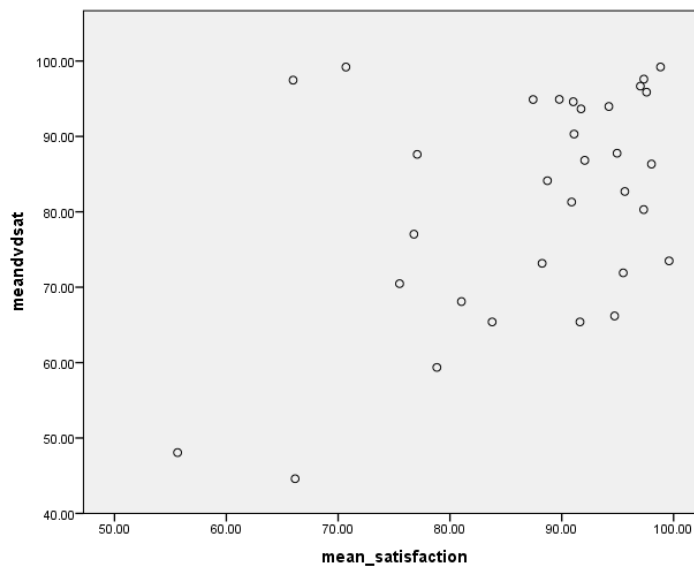
The correlation between satisfaction with the DVD and general satisfaction with clinic/standard information was assessed for the experimental group.

Table 8.9: Correlation of DVD Satisfaction and General Satisfaction for the DVD (Experimental) group

Pair	N	Correlation	Sig.
DVD Satisfaction & General Satisfaction	32	0.313	0.081

A moderate positive correlation of 0.313 indicated that the participants in the DVD group that were generally satisfied with the consultation process and information provided were also satisfied with the DVD. This was not statistically significant ($p=0.081$). See Appendix 13 for complete data.

Figure 8.9: Graph showing correlation between DVD Satisfaction and General Satisfaction scores for the DVD (Experimental) group.



8.6 Correlation – Knowledge and Satisfaction

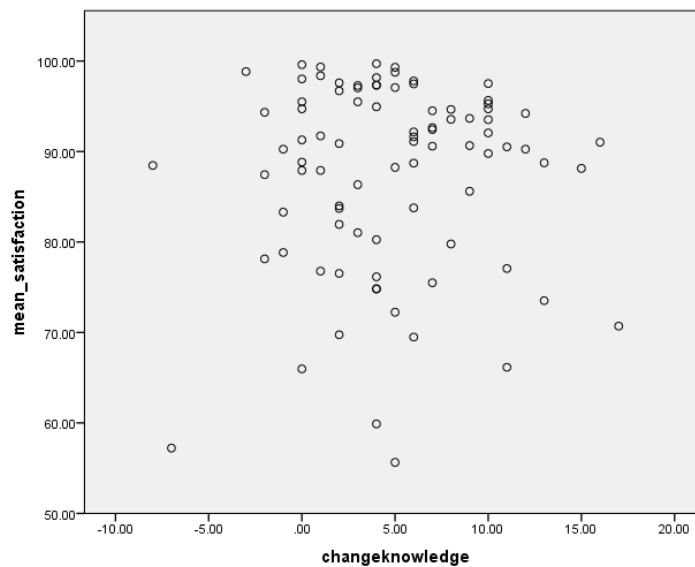
8.6.1 Change in Knowledge and General Satisfaction

Table 8.10 and Figure 8.10 show a weak negative association between change in knowledge and general satisfaction (-0.017) which suggests that as knowledge improved, general satisfaction with the information/clinic appointment decreased. However, this correlation was not statistically significant ($p=0.87$). See Appendix 14 for complete data.

Table 8.10: Correlation of Change in Knowledge and General Satisfaction

Pair	N	Correlation	Sig.
Change in knowledge & General Satisfaction	87	-0.017	0.87

Figure 8.10: Graph showing correlation between Change in Knowledge and General Satisfaction



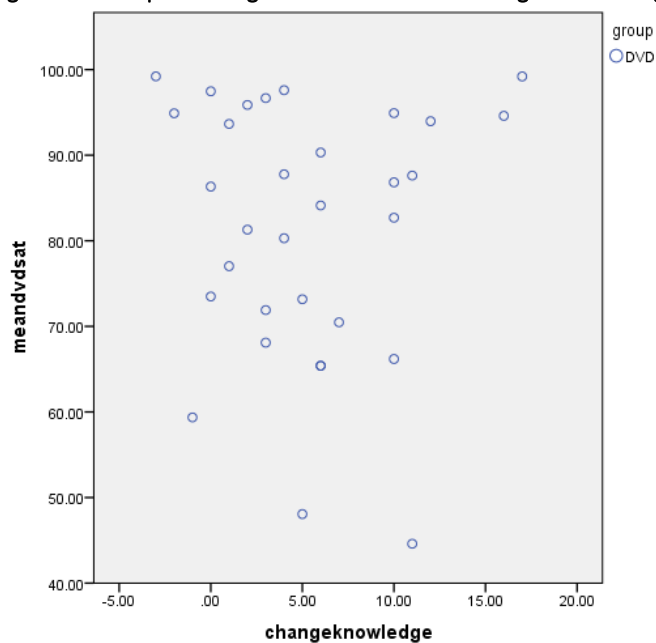
8.6.2 Change in Knowledge and DVD satisfaction

Table 8.11 and Figure 8.11 demonstrate a weak negative association between change in knowledge and DVD satisfaction (-0.084) which suggests that as participant knowledge improves they become less satisfied with the DVD. However, once again this was not found to be statistically significant $p=0.648$. See Appendix 15 for complete data.

Table 8.11: Correlation of Change in Knowledge and DVD Satisfaction for the DVD (Experimental) group

Pair	N	Correlation	Sig.
Change in knowledge & DVD Satisfaction	32	-0.084	0.648

Figure 8.11: Graph showing correlation between Change in Knowledge and DVD Satisfaction



8.7 Modified data

Three outliers were identified in the residuals of the data with the lowest scores were found. The data was re-run removing these outliers to assess whether the outliers affected the significance of the results.

Table 8.12: ANCOVA models for the effects of removal of outliers on follow-up knowledge score

Outcome	Effect of treatment (95% CI)	Overall effect of treatment	R ²	Covariate
Residuals of follow-up knowledge score	0.40 (-0.22, 1.01)	F(1, 81) = 0.43; p=0.837	0.169	Total baseline score

The p-value is still not significant so excluding the outliers made no difference to the significance of the results.

The residuals were tested for normality (excluding the outliers) using the Shapiro – Wilks test. The test statistic was 0.99 df 84 (p=0.809) which is not statistically significant so satisfies normality for residuals. See Appendix 16.

8.8 Harms

No harms were reported from participants in either the control or the intervention groups.

Chapter 9. Discussion

9.1 Summary of findings

1. There was no statistically significant difference in participants' knowledge of orthognathic treatment after receiving information in a standard format (verbal and written) alone or in a standard format with an additional DVD format.
2. Level of knowledge at baseline was significantly associated with follow-up level of knowledge.
3. There was no statistically significant difference in participants' general satisfaction with their MDT clinic appointment when given information after receiving information in a standard format alone or in a standard format with an additional DVD format. This suggests that both groups were equally satisfied with their MDT clinic appointment.
4. Participants in the DVD group were less satisfied with the DVD format than the standard information format/joint clinic appointment, suggesting the participants' may have preferred the face to face contact with the MDT team rather than the way in which the information was conveyed in the DVD which may have been perceived as being impersonal.
5. However, significantly more participants dropped out of the DVD group compared with the standard group.

9.2 Limitations of the study

9.2.1 Study duration

One factor that may have contributed to the lack of any significant differences being noted in knowledge score, may have been that the initial recruitment by GP, RG was slow with 44 participants (29 female and 15 male) being recruited between 5th March 2010 – 21st December 2012 (21 months). This could be attributed to the fact that no individual had a vested interest in arranging to attend MDT clinics to recruit patients. In 2013, EW was appointed as Chief Investigator to complete recruitment and analysis of the results of this study. Firstly, ethical approval was confirmed and updated. Careful organisation of clinical timetable was ensured to allow EW to attend clinics where possible and a research assistant was also provided to facilitate recruitment. This resulted in 62 participants (38 female and 24 male) being recruited between 12th May 2014 and 6th August 2015 (15 months).

The data was checked and no statistically significant difference was found between early and later cohort in terms of gender split ($p=0.583$) and age ($p=0.142$), therefore it was deemed appropriate that the data from both cohorts could be combined.

9.2.2 Sample size

The sample size calculation was based on a pilot study carried out within the department, and was determined acceptable to recruit 37 participant per group. However, this had to be increased to 48 participants per group (for

phase 1) to detect a difference of a difference of 2 points in the knowledge score with an 80% power at an alpha value of 0.05. This increase was to adjust for the drop out of treatment noted from the first cohort and in light of previous studies (O'Brien et al., 2009, Muqbil I, 2011). The final uptake of orthognathic treatment cannot be determined until the current cohort of patients have completed their treatment, at which point it will be possible to assess if the sample size has been achieved for phase 2 (uptake of treatment) and phase 3 (satisfaction with treatment) of the study.

9.2.3 Sample

Of the 106 participants, 63% were female (56% in control group and 70% in DVD group; OR 1.95, 95%CI 0.87, 4.36.) i.e., there were a larger proportion of females in the DVD group compared with the control group. This could be a potential source of bias present in the study however the differences may be representative of the gender differences of individuals obtaining orthodontic treatment. A similar proportion of female patients (65%) was observed by Al-Maaitah et al. (2011) who assessed 230 patients on completion of fixed orthodontic appliance treatment.

9.2.4 Blinding

The trial was single blinded, with only the assessor analysing the questionnaires blinded to the participants' treatment allocation until after the randomisation code was broken. Allocation concealment was carried out with sealed, opaque, sequentially numbered envelopes. It was not possible to blind the patient and or consultants, as the interventions were quite clearly different interventions/forms of information. However, the consultants did not

know the participant's allocation until after the MDT clinic so there should be minimal bias in terms of their verbal information provided at the clinic consultation.

9.2.5 Data collection

Patients were given a follow-up appointment 4-6 weeks after their initial consultation and asked to read/watch the information provided before their follow up appointment. They were not instructed exactly when in the six weeks to read the information so some may have watched or read the information more recently than others and therefore may do better which could potentially bias the results. However, importantly, this is likely to reflect what would occur in "real world" and gives an idea of "recall" which is an important aspect of valid consent.

9.2.6 Attrition bias

Significantly more participants dropped out of the DVD group than the control group so the trial may be subject to attrition bias (OR 3.45, 95%CI 1.23, 9.63.) The significant difference between the two groups in terms of 'loss to follow-up' may suggest that participants were put off treatment by the content on the DVD and decided not to proceed with orthognathic treatment so failed to attend follow-up appointments. As these patients are still on the waiting list to start treatment, it will be interesting to see whether they attend when called or whether they have really decided not to go ahead. If patients had chosen not to attend the review appointment, during which the follow-up questionnaire was administered, it would have been expected that the loss to follow-up at this stage would have been the same for both groups. As the

difference was significantly different it is possible to suggest that something, associated with the DVD, influenced participants to fail to attend. The difference may also have been related to an unknown confounding factor relating to the participants ability to attend appointments for social, personal or work-related reasons but again, due to the randomisation, these would have been expected to have been equally distributed between the groups.

The participants who did not attend their review appointment were sent two more review appointments, and sent the questionnaires to complete and return by post. However, those that did not attend/respond were reappointed in the next clinical session. Despite best efforts, this could introduce “non-response bias” or “performance bias” as the patients who complete the form at more than 4-6 weeks after the initial clinic consultation may forget more of the information. This highlights one of the difficulties often encountered when conducting trials. It remains unclear whether they still want to proceed with treatment and this will be investigated when these patients reach the top of the orthognathic treatment waiting list. Phase 2 and 3 of this study will assess uptake and satisfaction with orthognathic treatment between groups, after receiving information in a standard format (verbal and written) alone or in a standard format with an additional DVD format.

9.2.7 Bias by design

Interestingly, the last question on DVD satisfaction was reverse coded, and it scored much lower than the other two DVD questions which had similar scores to the general satisfaction scores. This question was:

16. The DVD gave me too much information.

**Strongly
agree**

**Strongly
disagree**

The low score could be an artefact of reverse coding/wording, as this is the only question where scoring to the left side of the VAS scale codes for a low mark. It would be expected that such a limitation would have been highlighted in the pilot study, however, this was not the case. It is possible that the participants did, in fact, feel the DVD has too much information as it covers all orthognathic treatment options. This could be important to realise when delivering patient information in other formats, such as via the Internet, and that there are separate sections clearly signposted so patients do not feel overwhelmed by the amount of information provided. Another downfall in the questionnaire is that there is no similar question regarding whether the MDT clinic consultation or the leaflet provided too much information, for comparison. There were comparison questions that asked the same question for the different information formats. Questions 10, 12 and 14 assessed whether the consultation, leaflet or DVD respectively “helped me understand my condition”. If we compare the median scores for this question, patients were actually more satisfied with the DVD 95.24%; consultation 92.31%; leaflet 91.43%. Question 11, 13, and 15 were similar questions regarding whether the consultation, leaflet or DVD respectively “helped me understand what will be involved in my treatment”. DVD and consultation scoring 95.48% and the leaflet score 92.38%. Please note that I

include this with caution as the questionnaire was not designed to compare individual questions and risk introducing a type I error due to multiple testing bias. But, it is of note as the last question is negatively worded and some questionnaires have a positive response to the DVD otherwise (in questionnaire 14 and 15) but a more unfavourable response to the final question. See Appendix 18.

A flaw in the design was that neither questionnaire assessed whether the participant actually read or watched the intervention (leaflet or DVD) they had been given. Perhaps those that didn't read/watch the leaflet/DVD didn't improve and those that did read/watch the leaflet/DVD.

9.3 Generalisability

9.3.1 Participants

The trial is likely to have good external validity within Mersey as it was a multi-centre study carried out at four hospitals within the region and involved experienced multi-disciplinary teams. How this relates to patients considering orthognathic treatment within the rest of the UK is uncertain. It is likely that the format of the MDT clinics is similar throughout the UK as orthognathic treatment is generally a hospital-based service in the UK led by consultant orthodontists and maxillofacial surgeons who have trained to the same speciality specific curricula and been examined in national Inter-collegiate Speciality Fellowship Examinations (ISFE).

9.3.2 Interventions

Consultants are likely to provide different information due to difference in their training. However, the standard information provided within each department's respective patient information leaflets (PILs) may differ, although many will use the leaflet written and distributed by the British Orthodontic Society. With respect to the patients attending these clinics, there may be a variation in baseline knowledge of patients around the country to the additional benefits that can be provided by the DVD may vary.

9.3.3 Setting

One limitation with the DVD on orthognathic surgery is that it is only in English, and so only relevant for use in the UK and internationally in countries who understand the English language. This will limit the potential impact the DVD can expect to have on the multi-cultured UK society. Consideration could be given to translating the DVD into other languages or providing subtitles in other common languages thereby making it more accessible to a greater number of patients. Any multimedia format necessitates the patient to have access to the multimedia platform concerned. Whilst DVDs are common place in today's society, it may be the case that not all patients have access to a DVD player at home, so this could be a barrier to their use. The ease of access to the internet in places of work, libraries, and schools as well as on mobile devices, has obviated the need for DVD players for some people. The internet is evolving very quickly and it may prove useful to have the DVD information on the internet for patients to access when they chose. Certainly the BOS has recently launched "Your Jaw Surgery" (<http://www.bos.org.uk/Public-Patients/Your->

[Jaw-Surgery¹](#)) which gives patients access to information on different types of jaw surgery together with video diaries of the patient journey and other recommended resources of information. This may prove to be a useful platform as information can be added or updated regularly and easily so as to provide the patients with the most up-to-date information. Patients can also access it anywhere, and have no need to have a DVD player. Yes, they need access to the internet, but it is potentially easier to get access to the internet at one of the aforementioned places, often for free. Certainly it would be useful to conduct a similar study on the information available online to see if patients find the added information useful in terms of knowledge and satisfaction, and how the access to information on the internet affected these outcomes.

9.4 Comparison with other studies

9.4.1 Knowledge

This study's results differ from previous literature, which have shown the positive effectiveness of multimedia visual aids in medical and surgical studies (Nozaki et al., 2007, Strevel et al., 2007, Ong et al., 2009, Wilhelm et al., 2009, , Smith et al., 2010, Solberg et al., 2010,). A greater improvement in knowledge, with provision of additional material, may have been expected in this study. However, there were limitations in some of the aforementioned study designs. Some of the studies did not validate their outcome measure (Wilhelm et al., 2009, Smith et al., 2010) and only one assessed content validity (Strevel et al., 2007). Wilhelm et al., (2009) and Smith et al., (2010) also omitted a sample size calculation which could lead to the studies being

underpowered. The DVD intervention did not result in an improvement in knowledge compared to the standard information. However, this maybe an underestimate as we do not know if all DVD participants did in fact watch the DVD as this question was not included in the questionnaire. It may also be that the general information was of sufficiently good quality that the DVD did not offer significantly more information than the combination of the written information leaflet and the information provided by the consultants at the new and MDT clinics. In addition, no time frame had been given to the participants on when to watch the DVD between the MDT and review appointments so some of the information may have been forgotten and therefore the effects of the DVD may have been lost in the time elapsed between appointments. However, this was an important 'real world' aspect of the trial as recall is important for informed consent especially when undergoing a long treatment plan.

Furthermore, there is still a chance that unknown confounding factors may have affected the results. Whilst randomisation of allocated participants should balance for both known and unknown confounders, there may still have been an unknown confounding factor that could have had an impact on the data. The attrition of participants at follow-up in this study was higher than initially expected, and the sample size was adjusted to account for this. There may have been reasons, unknown to the investigators, as to why these participants chose not to return. When this was examined, it was found that there was a significantly higher loss of participants in the DVD group OR (OR 3.45, 95%CI 1.23, 9.63). It may be postulated that the DVD provided

information that put the patients off continuing with treatment and that the patients' failure to return was a reflection their decision that they would prefer to stay as they were rather than embark on a long treatment plan with its inherent risks. It may, therefore, be suggested that the DVD gives 'too much' information however, it can also be argued that it is preferable to put patients off treatment before it starts rather than them abandoning treatment half way through by which time significant resources have been invested into the patients' treatment. It can also be proposed that the impact of any particular malocclusion will be different for every patient and at some point (Cunningham and O'Brien, 2007), the commitment needed and risks involved with orthognathic treatment become worse than the impact of the malocclusion at which point patients may be happier accepting their malocclusion.

Finally, in both groups, a small number of participants' knowledge scores reduced from baseline. This is unusual and was not expected as the participants had been given additional information, in either standard information or standard information plus the DVD. It is difficult to determine the cause for the intervention or the control resulting in a reduction in knowledge score unless participants simply forgot the information that had been provided. Knowledge decrease does occur with time but it would seem counterintuitive that the provision of more information would cause a decrease in knowledge unless that information was not read and/or watched. A number of reasons could be suggested as the cause for these results. The participants may have guessed the answer or misread the questions at either

visit, but this number is likely to be small and only on the odd question.

Other personal or social factors may result in low mood or enthusiasm by some participants when completing the questionnaire.

The results of the ANCOVA demonstrate that baseline knowledge scores significantly affected the final total follow-up score. It is, therefore, possible that those with the lowest baseline scores in knowledge have the most to gain from the additional information provided. This may be true for a number of reasons. Those with a lower baseline knowledge score, have the potential to have a greater improvement in knowledge score compared with those who already start with a high baseline score. Those with a higher baseline score may have already researched orthognathic treatment prior to their MDT clinic consultation and reached saturation point so may not have been as interested in gaining additional information or relatively, have as much knowledge to gain from the additional information provided.

9.4.2 Satisfaction

General satisfaction scores in the Standard information and DVD groups were not statistically significant (90.97% and 89.78%; (Mann–Whitney $U=821.0$, $n_1=46$ $n_2=41$, $P=0.3$ two-tailed), suggesting that both groups were equally satisfied with their MDT clinic appointment. It was expected that there would be a difference in satisfaction when providing additional information in different format. This difference could have been positive with participants feeling they had been provided with enough/additional information, or negative if they felt they had been given too much or too little information. However, this study demonstrated no difference in participants'

general satisfaction scores. This is likely due to the general satisfaction questions being related to the written information and clinic consultation itself, rather than the additional information in DVD format. The DVD therefore may not have had any effect on general satisfaction as these questions were separate. In addition, some patients who had been given the DVD may not have watched the DVD so any additional benefit would not have been gained. A question as to whether the patients had or had not watched the DVD they had been given may have useful information for assessing this effect. Finally, there may also have been unknown confounding factors not accounted for that may have contributed to this effect.

There was, however, a significant reduction in score on the DVD satisfaction compared with general satisfaction, i.e. participants were less satisfied with the DVD format than the standard information format/joint clinic appointment. This suggests that the participants may have preferred the face to face contact with the MDT team rather than the way in which the information was conveyed in the DVD which may have been perceived as being impersonal. This has implications for the provision of orthognathic treatment. It suggests that patients may get benefit and actually prefer discussing their care with their clinicians who can then tailor the information to each and every patient's individual needs, concerns and questions.

The correlation between satisfaction with the DVD and general satisfaction with clinic/standard information was assessed for the experimental group. A moderate positive correlation of 0.386 indicated that the participants in the

DVD group were generally satisfied with the consultation process and information provided and were also satisfied with the DVD. This was statistically significant ($p=0.029$). It may be that these participants had a personally trait where they are generally satisfied or optimistic about most things and so this affected results in both general and DVD satisfaction. Further to this, general satisfaction with the MDT clinic appointment may have led to satisfaction with the DVD information. The opposite may also be true that satisfaction with the DVD information may lead to increased general satisfaction levels with the whole process. It is difficult to determine exactly where the effect lies with these results, and would be difficult to design a study to show this as much of the satisfaction with care received are interdependent. Weak negative associations between change in knowledge and both general satisfaction were found but these were not statistically significant.

Although there were no differences between the knowledge scores in both groups, they had similar satisfaction scores and the DVD could be effective for some participants so it is still a useful adjunct and participants can be informed about the option of using the DVD to aid their understanding of their treatment and decision making.

9.5 Other information

9.5.1 Registration

The REC reference number for the study was 08/H1005/75.

9.5.2 Protocol

This project was awarded the British Orthodontic Society Protocol Prize to the value of £500.

9.5.3 Funding

The protocol for this RCT was awarded the British Orthodontic Society Protocol Prize (£500) which part-funded the cost of then DVDs.

The University of Liverpool paid for the remainder of the cost of the DVDs provided in the information packs.

Chapter 10. Conclusions

The conclusions of this research are:

- 1. There was no difference in participants' knowledge of orthognathic treatment after receiving information in a standard format (verbal and written) alone or in a standard format with an additional DVD format.**
- 2. Level of knowledge at baseline was significantly associated with follow-up score.**
- 3. There was no statistically significant difference in participants' general satisfaction with their MDT clinic appointment when given information after receiving information in a standard format (verbal and written) alone or in a standard format with an additional DVD format.**
- 4. Participants in the DVD group were less satisfied with the DVD format than the standard information format/joint clinic appointment.**

Chapter 11. Implication for clinical practice

The results of the study have implications for the provision of orthognathic treatment.

The DVD could potentially be used as a routine supplement for patients considering orthognathic treatment and may be a useful adjunct. Perhaps give it to them before putting them on the waiting list or giving them the time and space to watch it in the hospital so that it does not have to compete with other viewing demands in the home environment.

However, the results suggest that patients may get benefit and actually prefer discussing their care with their clinicians who can then tailor the information to each and every patient's individual needs, concerns and questions.

It may be suggested that the DVD gives 'too much' information however, it can also be argued that it is preferable to put patients off treatment before it starts rather than them abandoning treatment half way through by which time significant resources have been invested into the patients' treatment.

It shows a need to focus on patient centred outcomes and ensure consultation from patients on the quality of information provision and how best to deliver pre-treatment information and if that impacts on patient satisfaction and knowledge.

Chapter 12. Implications for research

Following this study, the recommendations for future research studies are:

1. Phase 2 and 3 of this trial are ongoing and focus on the differences between the two intervention groups and:
 - their uptake of treatment (phase2 -medium term), and
 - satisfaction with the final outcome of their treatment (phase 3 - long term).
2. Qualitative research project to assess why some patients do not proceed to take up treatment.
3. With ongoing technological advancements, internet or mobile app based information could be explored to assess improvements in patient's knowledge and/or satisfaction with patient centred-outcomes. Incorporating qualitative ideas and/or free text for patient feedbacks/suggestions/improvements.

Additions to the evidence available would allow us to understand patients' knowledge and attitudes towards orthognathic surgery and help develop information regarding such treatment and how best to inform patients'.

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Appendices

Appendix 1. Cover letter



Dear

We note that you have an appointment on the Joint Orthodontic (brace) and Orthognathic (jaw surgery) Clinic.

We would, therefore, like to invite you to take part in our research study that is looking at whether patients are happy with the normal way we give them information about their treatment i.e. through a discussion at their appointment and a written information leaflet or whether patients find watching a DVD on orthodontic treatment and jaw surgery as well, more helpful.

This study is being sponsored by the Royal Liverpool and Broadgreen trust.

If you chose not to take part in our study, this will not affect the standard of care you will receive. If you do take part in the study, all the information that we collect will be kept confidential.

We have enclosed an information leaflet about our study to help you make your decision.

If you have any further questions we will be happy to help answer them when you attend the clinic. We look forward to seeing you.

Kind regards.

Yours sincerely,

Miss Eileen Watt

Specialist Registrar in Orthodontics

Dr Jayne Harrison

Consultant Orthodontist

A member of the
Russell Group

Appendix 2. Information leaflet about study

PATIENT INFORMATION LEAFLET

Orthognathic (Jaw) Surgery DVD Study



A member of the
Russell Group

You are being invited to take part in a research study that is looking at whether patients are happy with the normal way we give them information, through a discussion at their appointment and a written information leaflet or whether patients find watching a DVD (on orthodontic (brace) treatment and jaw surgery) as well, more helpful.

Before you decide whether to take part in the study or not, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Please take your time in deciding whether or not you wish to take part in the study.

What is the purpose of this study?

Patients are increasingly looking for extra information about their treatment from a variety of sources. In order to meet needs of patients thinking about having brace treatment and jaw surgery to correct their bite and facial appearance, the British Orthodontic Society has produced a DVD. This DVD has been made to help patients understand what is involved in this type of treatment and what to expect

This study aims to assess how good the DVD is at informing patients about their jaw surgery and brace treatment and whether this affects how satisfied they are with their initial appointments.

If the DVD is found to be helpful, then a copy of the DVD will be given to all patients thinking about having this treatment.

Why have I been chosen?

You have been referred to the joint orthodontic and jaw surgery clinic because your dentist or orthodontist feels that you may benefit from treatment that will change the position of your teeth and jaws.

All adults over the age of 16 years attending these joint clinics are being invited to take part in this study. A minimum of 56 patients will be needed for this study to be worthwhile.

Do I have to take part in this study?

It is up to you to decide whether or not to take part in this study. If you do decide to take part, you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you decide to withdraw at any time or do not wish to take part, this will not affect the standard of care you will receive.

What will happen to me if I take part?

If you take part in this study, when you attend the joint orthodontic and jaw surgery clinic, you will be allocated into one of two study groups. Neither you, nor your clinicians, will be able to choose which group you go into. This decision will be made in a way similar to tossing a coin.

- **Group 1 (standard care group)** – you will have a discussion with your orthodontist and surgeon about your planned treatment and receive a written information leaflet about orthodontics and jaw surgery.

- **Group 2 (trial group)** - you will have a discussion with your orthodontist and surgeon about your planned treatment and receive a written information leaflet and DVD about orthodontics and jaw surgery.

We want to find out how much information about the treatment you have understood and how satisfied you are with your initial clinic appointments. This will be done using two short questionnaires. One questionnaire will be completed before you are seen on the joint clinic and the other at the next review appointment. We will then try and find out which group of patients understands the most about their treatment and is most satisfied with their clinic appointments.

Patients taking part in the study will not have to attend for any extra appointments.

What are the risks and disadvantages of taking part?

There do not appear to be any risks or disadvantages if you take part in this study. However, some patients may find the information in the DVD off-putting whilst others might find it helpful. This study aims to find out what patients find most helpful. The main difference between taking part or not, is that you will need to spend a few minutes completing the questionnaires at your appointments and one group will need to spend some time at home watching the DVD.

What are the possible benefits of taking part?

It is possible that if you are allocated to the trial group, you may find the DVD helpful in understanding your condition and the available treatments. However, this cannot be guaranteed. As the allocation to the control/trial group is carried out randomly by a computer, we cannot put you into the group of your choice as this will affect the results of the study.

Will my taking part in the study be kept confidential?

The health professionals involved in this study will need access to your dental, orthodontic and hospital records and the information collected in this study. However, all information which is collected during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised by it.

What will happen to the results of the study?

The results of this study will form part of a research dissertation and will be published in an international dental journal. The results may also be presented at professional dental meetings. As mentioned above, your confidentiality is important and you will not be identified by name in any publication or presentation.

Who is funding the research?

The British Orthodontic Society Foundation will be funding the research.

Has the study been approved?

Yes. A local research and ethics committee have approved this study.

Contact for further information

If you have any further questions or want to discuss the study, please contact Mrs Eileen Watt on 0151 706 5252 (an answering machine service is available) or write to her at:

Orthodontic Department
Liverpool University dental Hospital
Pembroke Place
Liverpool
L3 5PS

Thank you very much for taking time to read this leaflet and we hope you will consider taking part in this study.

You will be given a copy of this information leaflet and a signed consent form to keep

Appendix 3. Consent form

CONSENT FORM

A Randomised Controlled Trial to assess how good a DVD is at informing patients about their jaw surgery and brace treatment and whether this affects how satisfied they are with their initial appointments.

Please answer each question by ticking the YES or NO box

- I have read and understood the information sheet provided
- I have received enough information about this study
- I have been given the opportunity to ask questions and discuss this study
- All of my questions have been answered satisfactorily
- I understand that my participation is voluntary and that I can withdraw from this study...
 - At any time
 - Without giving a reason
 - Without affecting my future dental or surgical or orthodontic care

YES	NO

I agree to take part in this study.

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_____ Name of Patient	_____ Signature	_____ Date
_____ Name of Clinician	_____ Signature	_____ Date
Copy given to participant		

YES	NO

Appendix 4. Patient information leaflet on orthognathic surgery

The Royal Liverpool and 
Broadgreen University Hospitals
NHS Trust

LIVERPOOL UNIVERSITY DENTAL HOSPITAL

PATIENT INFORMATION

ORTHOGNATHIC SURGERY AND ORTHODONTICS

If you are considering having orthodontics (treatment of improper bites) and orthognathic Surgery (jaw surgery) you may have some questions that you would like answered.

If I need jaw surgery, why do I also need orthodontics?

At the moment, your teeth and jaws are in the wrong position so if your jaws were moved to the correct position without also moving your teeth, then your teeth wouldn't bite together properly after the operation. It is important that your teeth are moved into the correct position using orthodontic braces, before surgery, so that they bite together properly when your jaws are in the right position after your operation. Orthodontic treatment is therefore necessary to allow your teeth to meet properly after the operation and help you to get the most benefit from your operation.

If your jaws are not in the correct position, orthodontics on its own may not be able to correct your bite properly or change your facial appearance if this is of concern to you. This means you will need surgery to correct the position of your jaws and allow your teeth to meet correctly.

What is involved in the treatment?

Firstly, your orthodontist or maxillofacial surgeon will see you to find out what concerns you about your teeth, bite and/or face; examine your teeth and face and perform tests. These tests may include models of your teeth, (x-rays) of your teeth and jaws and photographs of your teeth and face.

You will then be seen by your orthodontist and maxillaofacial surgeon together at a joint clinic to discuss and explain your treatment further. After this, if you want to go ahead

with the treatment, you will have a fixed brace fitted on to your teeth. This brace will move your teeth into positions that will be correct once the jaw surgery has been completed but may make your bite worse at first. Once your fixed brace has been fitted, you will need regular appointments every six to eight weeks, so that your brace can be adjusted. However, these appointments will be more often around the time of your operation.

Once your teeth are in the correct position you will be seen at a joint clinic again for the final planning. Immediately before your operation, it is likely that you will need more records taking and tests done, e.g. blood tests and you will meet with the anaesthetist. You will then have your surgery carried out after which your orthodontist will continue your orthodontic treatment to get your teeth meeting together in the best possible way.

When your jawbones have healed in their new position and when your teeth are biting together well, your orthodontist will remove your fixed brace and provide you with retaining braces.

What type of brace will I need to wear?

Your orthodontist will use fixed braces to move your teeth before jaw surgery because they allow the most accurate positioning of your teeth.

Will my braces be removed before the operation?

No, your braces stay in position during and for about six to nine months after your operation. During your operation, your surgeon will use them to help position your jaws correctly. Your orthodontist will then use them after your operation to help fine tune your bite.

Will I be given anaesthesia?

Yes. You will need to have a general anaesthetic for the operation so you will be asleep when it is done. A general anaesthetic is drug-induced unconsciousness. An anaesthetist, who is a doctor with specialist training, always provides it. Unfortunately, general anaesthetics can cause side effects and complications. Side effects are common, but are usually short-lived: they include nausea, sickness, confusion and pain. Complications are rare, but can cause lasting injury. They include awareness, paralysis and extremely rarely, death.

The risks of anaesthesia and surgery are lower for people who are young, fit, active and well. You will be given an opportunity to discuss anaesthetic options and risks before

your surgery. For more information please ask for a copy of the leaflet **“You and Your Anaesthetic”** (PIF 344).

How will the surgeon do my operation?

Your surgeon will do most of the operation from inside your mouth. This will mean that it is unlikely that you will have any scars on your face. Your surgeon will make cuts in your gums. If you are having an operation on your top jaw, the cuts will be high up under your top lip. If you are having an operation on your bottom jaw, the cuts will be behind and along the cheek side of your back teeth. Your surgeon will then cut your jawbones and move them to their new positions. Once the jawbones are in the correct position, your surgeon will fix them in place with small metal plates and screws and then sew your gums back together.

How long will I be in hospital?

This varies, but in general between three to five days. Usually you come into hospital the day before the operation and leave two to three days after the operation.

How will my jaws stay in their new position?

During your operation your surgeon will place plates and screws to fix your jaws together in their new position. Usually the jaws are quite stable. However, occasionally (about 10%) the jaws can move after the operation (relapse). The relapse is usually only small and does not affect the result of the treatment significantly. Very occasionally (about 1%) the relapse is greater. If this is the case you may need to have your operation redone. Your surgeon will discuss this with you if necessary.

It is unlikely that your jaws will be wired together. In the past, patients having jaw surgery had their teeth wired together for six to eight weeks after their operation.

However, this is unusual now because your surgeon will use small metal plates and screws to hold your jaws in their new position. Nevertheless, you may need to wear light elastic bands, between your top and bottom teeth, after the operation to help guide your teeth and jaws into the correct position.

The plates lie on the surface of the bone but under the skin and usually remain in place forever. Occasionally, (about 10%) the plates or screws become infected or loose and it may be necessary to remove them. Your surgeon will discuss it with you if necessary.

Are there any risks or side effects?

As with any operation, there are general after effects related to the anaesthetic and having any operation as well as after effects and risks specific to jaw surgery.

Risks specific to having jaw surgery, include swelling and/or bruising of your face immediately after the operation and numbness or altered feeling of your face. The swelling usually goes down rapidly over the first two to three weeks after the operation and then continues to reduce more slowly over the next six to nine months. The bruising has usually gone by four weeks after the operation.

Where you get numbness depends on which jaw is operated on. If you have an operation on your lower jaw, it is likely that your lower lip and chin will be numb or tingly for some weeks or months after the operation. In a very small number of cases (about 10%) a small area of altered feeling or numbness will remain. If you have an operation on your top jaw, your cheeks and the sides of your nose may be affected in this way after the operation.

This numbness will **not** affect the movement of your face but only the feeling in it. You will still be able to move your lips, cheeks and chin normally but they will feel a little odd (like when you have had an injection at the Dentist), when you wash, shave or put your make-up on.

Sometimes, when you are eating or drinking, you may not notice any food or drink that falls on the affected area.

Very rarely, more serious complications e.g. excessive bleeding, deep vein thrombosis, pulmonary embolism, heart attack or loss of sight can occur.

Jaw surgery is a major operation so you will need to take it easy for the two or three weeks afterwards. You should therefore expect to be off school / college / work for at least this length of time.

Are there any alternatives to orthognathic surgery?

If you are happy with your bite and facial appearance but don't like your teeth, then it may be possible to straighten your teeth on their own accepting that your bite and face will not change. You can discuss this with your orthodontist.

If you would like the treatment but feel that the time is not right for you just now, then it is possible for you to delay having it done until you feel ready to go ahead with treatment. You can discuss this with your orthodontist or surgeon.

Will I look very different after the operation?

After your operation your face is likely to be very swollen so you will look different.

Once the swelling has gone down you will almost certainly look different, but it is hard to say exactly how you will look compared to how you looked before your operation. This usually depends on how much your jaws have been moved. You should discuss this with your orthodontist or maxillofacial surgeon.

How long will my treatment take?

Your treatment is likely to take 24 to 36 months but will vary according to how severe your case is. There will be about 18 to 24 months orthodontic treatment before your operation and then about 6 to 12 months afterwards. Once your fixed braces have been removed you will be given retainer braces to wear for at least 12 months. See patient information leaflet PIF 198 **Retainers**. If you fail and/or cancel your appointments or repeatedly break your brace you will increase the time your treatment takes.

Will I be able to eat and drink normally?

You should be able to eat and drink nearly normally during your orthodontic treatment. For your orthodontic treatment to work well and in the shortest possible time it is important you take care of your teeth and brace. In order to prevent damaging them you should avoid the following:

- Toffees, boiled sweets, chewing gum, chocolate bars, etc.
- Fizzy drinks including diet drinks, excessive amounts of fruit juice.
- Hard foods which might damage the brace, such as crunchy apples, crusty bread rolls etc.

You can eat hard foods if you take care, for example by cutting them up first.

After your operation, you will need a softer diet. For the first few days this will be liquid and then you can build up to soft foods such as scrambled eggs, pasta or mince and mashed potato. The dietician at the hospital will advise you about this nearer the time.

What about brushing my teeth?

If you don't keep your teeth and brace clean your teeth may become damaged, leaving white or brown spots around where your brace has been. It is really important to brush your teeth well, at least twice a day with fluoride toothpaste, to stop this happening. If possible carry a toothbrush with you to use after lunch and during the day if necessary. You can also use a daily fluoride mouth rinse to help protect your teeth further.

Immediately after your operation it will be difficult for you to brush your teeth. For the first few days, you will be given mouth sponges to clean your mouth and teeth. After this you will need to start brushing your teeth with a small (child's) toothbrush.

How often will I need an appointment?

Before you start any treatment there will be several planning appointments where your orthodontist and/or surgeon will plan and discuss your treatment with you. This will also give you the opportunity to ask any questions you may have. Once your have had your brace fitted, you will need regular appointments, about every six to eight weeks, for it to be adjusted. However, around the time of surgery your orthodontist and surgeon will need to see you more frequently.

Do I still need to see my regular dentist?

Yes. It will be important for you to have check-ups with your regular dentist throughout your orthodontic treatment. Your orthodontist will not be checking your teeth for decay.

What do I do if I play contact sports?

You should wear a mouth guard over your fixed appliance when you play contact sports before you have your operation.

After the operation, you shouldn't play any contact sports for at least six months to avoid damaging the bones. This should be the same if you had broken your arm or leg in an accident.

Other advice

If you are planning on going on holiday after your operation you are advised not to travel by air for at least three months after having surgery.

Further Information

If you have any other questions that you feel you would like to ask, then please write them down and bring them with you to your next appointment. It is important that you fully understand what is involved in having such treatment before you decide to go ahead.

Orthodontic Department

Liverpool University Dental Hospital

Date: June

2008

Review date: June 2010

This leaflet is available in large print, computer disc, Braille, audiocassette and other languages on request.

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Appendix 5. Knowledge Questionnaire

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Baseline ☐ Follow-up ☐

Orthognathic (jaw) surgery DVD study

ID No.

TO ANSWER EACH QUESTION, PLEASE MARK THE RELEVANT BOX WITH A CROSS IN BLACK PEN LIKE THIS ☒

1. If your jaws are not in the correct position, surgery and orthodontics may help improve your bite and appearance. ☐ True ☐ False ☐ Unsure
2. You will probably need to wear fixed braces before and after surgery. ☐ True ☐ False ☐ Unsure
3. You will only need to attend a couple of appointments to have your brace adjusted. ☐ True ☐ False ☐ Unsure
4. You are likely to need to have photos, x-rays and models taken of your teeth, jaws and face to help plan your surgery. ☐ True ☐ False ☐ Unsure
5. Routine tests, for example blood tests, don't need to be carried out before your surgery. ☐ True ☐ False ☐ Unsure
6. You will be awake during your surgery. ☐ True ☐ False ☐ Unsure
7. During surgery your jaw bones will be divided and moved to their new position. ☐ True ☐ False ☐ Unsure
8. General anaesthetics can cause side effects and serious complications. ☐ True ☐ False ☐ Unsure
9. The cuts for your surgery will probably be made from inside your mouth. ☐ True ☐ False ☐ Unsure
10. If your surgery needs to be done through a cut in your skin, it will be done through a skin crease to make the scar less obvious. ☐ True ☐ False ☐ Unsure
11. During your surgery, your jaw bones will be secured with metal plates and screws which will be removed once your bones have healed. ☐ True ☐ False ☐ Unsure
12. The plates in your jaw bones may need to be removed if they become infected. ☐ True ☐ False ☐ Unsure
13. After the surgery your top and bottom jaws will be wired together. ☐ True ☐ False ☐ Unsure

PLEASE TURN OVER



53929

Orthognathic (jaw) surgery DVD study

14. You will be in hospital for around 3 to 5 days.	<input type="checkbox"/> True <input type="checkbox"/> False <input type="checkbox"/> Unsure
15. If you have surgery on your lower jaw, you probably will have a numb lower lip and chin immediately after your surgery.	<input type="checkbox"/> True <input type="checkbox"/> False <input type="checkbox"/> Unsure
16. Your face and mouth won't swell up after the surgery.	<input type="checkbox"/> True <input type="checkbox"/> False <input type="checkbox"/> Unsure
17. If you have surgery on your top jaw, your cheeks and nose won't be numb or feel odd after the operation.	<input type="checkbox"/> True <input type="checkbox"/> False <input type="checkbox"/> Unsure
18. You will be able to move your cheeks and lips normally after the surgery.	<input type="checkbox"/> True <input type="checkbox"/> False <input type="checkbox"/> Unsure
19. Numbness can last for a few weeks or months, but it won't be permanent.	<input type="checkbox"/> True <input type="checkbox"/> False <input type="checkbox"/> Unsure
20. You will need a liquid diet immediately after the surgery and then a soft diet while your jaws heal.	<input type="checkbox"/> True <input type="checkbox"/> False <input type="checkbox"/> Unsure
21. You will need to keep your teeth clean whilst wearing your brace to prevent them from being damaged around where the brace has been.	<input type="checkbox"/> True <input type="checkbox"/> False <input type="checkbox"/> Unsure
22. You will look the same after the operation.	<input type="checkbox"/> True <input type="checkbox"/> False <input type="checkbox"/> Unsure
23. You won't need to take any time off from school/college or work after the operation.	<input type="checkbox"/> True <input type="checkbox"/> False <input type="checkbox"/> Unsure
24. Once your fixed brace is removed, you will need to wear retainers to keep your teeth in their new position.	<input type="checkbox"/> True <input type="checkbox"/> False <input type="checkbox"/> Unsure
25. You can play contact sports as soon as you like after your operation.	<input type="checkbox"/> True <input type="checkbox"/> False <input type="checkbox"/> Unsure
26. The whole of your treatment is likely to take 12 to 18 months.	<input type="checkbox"/> True <input type="checkbox"/> False <input type="checkbox"/> Unsure
27. You won't need to go for regular check-ups at your own dentist whilst you are having brace treatment.	<input type="checkbox"/> True <input type="checkbox"/> False <input type="checkbox"/> Unsure

Thank you for taking part in this study

Appendix 6. Satisfaction Questionnaire

Orthognathic (jaw) surgery DVD study.

To answer to each question, please mark the relevant line with an X e.g.

Strongly
agree

Strongly
disagree

X

1. After talking to the orthodontist and surgeon, I know what condition my mouth is in.

Strongly
agree

Strongly
disagree

2. After talking with the orthodontist and surgeon, I have a good idea of what changes to expect to my teeth and jaws.

Strongly
agree

Strongly
disagree

3. The orthodontist and surgeon told me all I wanted to know about my orthodontic and jaw problems.

Strongly
agree

Strongly
disagree

4. I felt really understood by my orthodontist and surgeon.

Strongly
agree

Strongly
disagree

5. I felt that the orthodontist and surgeon really understood my concerns about treatment.

Strongly
agree

Strongly
disagree

6. I felt that the orthodontist and surgeon accepted me as a person.

Strongly

Strongly

agree	disagree
<hr/>	
7. The orthodontist and surgeon were thorough in the examination.	
Strongly	Strongly
agree	disagree
<hr/>	
8. I was satisfied with what the orthodontist and surgeon did today.	
Strongly	Strongly
agree	disagree
<hr/>	
9. The orthodontist and surgeon seemed to know what they were doing during my visit.	
Strongly	Strongly
agree	disagree
<hr/>	
10. Talking with the orthodontist and surgeon helped me understand my condition.	
Strongly	Strongly
agree	disagree
<hr/>	
11. Talking with the orthodontist and surgeon helped me understand what will be involved in my treatment.	
Strongly	Strongly
agree	disagree
<hr/>	
12. Reading the patient information leaflet helped me understand my condition.	
Strongly	Strongly
agree	disagree
<hr/>	
13. Reading the patient information leaflet helped me understand what will be involved in my treatment.	
Strongly	Strongly
agree	disagree
<hr/>	

**FOR PATIENTS WHO WATCHED THE DVD ON ORTHOGNATHIC (JAW) SURGERY PLEASE
ALSO ANSWER THE FOLLOWING QUESTIONS**

14. Watching the DVD helped me understand my condition.

Strongly

Strongly

agree

disagree

15. Watching the DVD helped me understand what will be involved in my treatment.

Strongly

Strongly

agree

disagree

16. The DVD gave me too much information.

Strongly

Strongly

agree

disagree

Appendix 7. Letter for request of completion of questionnaire



Dear

Further to your Joint Orthodontic (brace) and Orthognathic (jaw surgery) Clinic where you very kindly agreed to take part in our research study that is looking at whether patients are happy with the normal way we give them information about their treatment i.e. through a discussion at their appointment and a written information leaflet or whether patients find watching a DVD on orthodontic treatment and jaw surgery as well, more helpful.

Please find enclosed two (double-sided) questionnaires for you to complete and return to me in the envelope provided.

If you have any further questions we will be happy to help answer them when you attend the clinic. We look forward to seeing you.

Kind regards.

Yours sincerely,

Miss Eileen Watt
Specialist Registrar in Orthodontics

Dr Jayne Harrison
Consultant Orthodontist

Appendix 8. Baseline and Follow-up Knowledge Data

Descriptives

	group		Statistic	Std. Error
Totalbaseline	DVD	Mean	14.26	.737
		95% Confidence Interval for Mean	Lower Bound 12.78	
		Upper Bound	15.74	
		5% Trimmed Mean	14.44	
		Median	15.00	
		Variance	28.813	
		Std. Deviation	5.368	
		Minimum	0	
		Maximum	23	
		Range	23	
		Interquartile Range	8	
		Skewness	-.439	.327
		Kurtosis	-.461	.644
	STND	Mean	15.31	.686
		95% Confidence Interval for Mean	Lower Bound 13.94	
		Upper Bound	16.69	
		5% Trimmed Mean	15.36	
		Median	15.00	
		Variance	23.980	
		Std. Deviation	4.897	
		Minimum	3	
		Maximum	25	
		Range	22	
		Interquartile Range	8	
		Skewness	-.144	.333
		Kurtosis	-.516	.656

Appendix 9. Baseline and Follow-up Knowledge Data

Descriptives

	group		Statistic	Std. Error
Totalfollowup	DVD	Mean	19.54	.620
		95% Confidence Interval for Mean	Lower Bound 18.28	
			Upper Bound 20.79	
		5% Trimmed Mean	19.87	
		Median	20.00	
		Variance	15.755	
		Std. Deviation	3.969	
		Minimum	5	
		Maximum	25	
		Range	20	
		Interquartile Range	4	
		Skewness	-1.497	.369
		Kurtosis	3.365	.724
	STND	Mean	20.09	.565
		95% Confidence Interval for Mean	Lower Bound 18.95	
			Upper Bound 21.22	
		5% Trimmed Mean	20.40	
		Median	20.50	
		Variance	14.659	
		Std. Deviation	3.829	
		Minimum	5	
		Maximum	26	
		Range	21	
		Interquartile Range	4	
		Skewness	-1.513	.350
		Kurtosis	4.483	.688

Appendix 10. Analysis of Covariance

Between-Subjects

Factors

		N
group	DVD	41
	STND	46

Tests of Between-Subjects Effects

Dependent Variable: Totalfollowup

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	134.549 ^a	2	67.274	8.260	.001
Intercept	1947.451	1	1947.451	239.118	.000
group	.346	1	.346	.043	.837
Totalbaseline	132.058	1	132.058	16.215	.000
Error	659.689	81	8.144		
Total	35280.000	84			
Corrected Total	794.238	83			

a. R Squared = .169 (Adjusted R Squared = .149)

Appendix 11. Residuals for follow-up

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Residual for Totalfollowup	87	82.1%	19	17.9%	106	100.0%

Descriptives

			Statistic	Std. Error
Residual for Totalfollowup	Mean		.0000	.37691
	95% Confidence	Lower Bound	-.7493	
	Interval for Mean	Upper Bound	.7493	
	5% Trimmed Mean		.1822	
	Median		.3905	
	Variance		12.359	
	Std. Deviation		3.51555	
	Minimum		-13.60	
	Maximum		7.06	
	Range		20.66	
	Interquartile Range		3.99	
	Skewness		-1.025	.258
	Kurtosis		2.732	.511

Appendix 12. General Satisfaction Data

	group	Cases					
		Valid		Missing		Total	
		N	Percent	N	Percent	N	Percent
mean_satisfaction	DVD	41	75.9%	13	24.1%	54	100.0%
	STND	46	88.5%	6	11.5%	52	100.0%

Descriptives

	group		Statistic	Std. Error
mean_satisfaction	DVD	Mean	85.8587	1.88307
		95% Confidence Interval for Mean	Lower Bound 82.0529	
			Upper Bound 89.6645	
		5% Trimmed Mean	86.7488	
		Median	89.7802	
		Variance	145.383	
		Std. Deviation	12.05750	
		Minimum	55.64	
		Maximum	99.60	
		Range	43.96	
		Interquartile Range	17.27	
		Skewness	-1.105	.369
		Kurtosis	.335	.724
	STND	Mean	89.1296	1.27311
		95% Confidence Interval for Mean	Lower Bound 86.5654	
			Upper Bound 91.6937	
		5% Trimmed Mean	89.6095	
		Median	90.9707	
		Variance	74.558	
		Std. Deviation	8.63468	
		Minimum	69.49	
		Maximum	99.71	
		Range	30.22	
		Interquartile Range	12.54	

	Skewness	- .807	.350
	Kurtosis	- .438	.688

Appendix 13. General Satisfaction Mann-Whitney U Wilcoxon

Ranks				
	group2	N	Mean Rank	Sum of Ranks
mean_satisfaction	DVD	41	41.02	1682.00
	STND	46	46.65	2146.00
	Total	87		

Test Statistics ^a	
	mean_satisfaction
Mann-Whitney U	821.000
Wilcoxon W	1682.000
Z	-1.037
Asymp. Sig. (2-tailed)	.300

a. Grouping Variable: group2

Appendix 14. DVD satisfaction

	Cases					
	Included		Excluded		Total	
	N	Percent	N	Percent	N	Percent
meandvdsat * group2	32	30.2%	74	69.8%	106	100.0%

meandvdsat

group2	Mean	N	Std. Deviation	Median	Std. Error of Mean	Minimum	Range	Maximum
DVD	81.5162	32	14.91568	85.2285	2.63674	44.60	54.61	99.21
Total	81.5162	32	14.91568	85.2285	2.63674	44.60	54.61	99.21

Descriptives

	group	Statistic	Std. Error
meandvdsat	DVD	Mean	81.5162
		95% Confidence Interval for Mean	2.63674
		Lower Bound	76.1386
		Upper Bound	86.8939
		5% Trimmed Mean	82.5122
		Median	85.2285
		Variance	222.477
		Std. Deviation	14.91568
		Minimum	44.60
		Maximum	99.21
		Range	54.61
		Interquartile Range	24.00
		Skewness	-.814
		Kurtosis	.809

Appendix 15. General satisfaction and DVD satisfaction

Correlations

			mean_satisfaction	meandvd satisfaction
Spearman's rho	mean_satisfaction	Correlation Coefficient	1.000	.313
		Sig. (2-tailed)	.	.081
		N	87	32
	meandvd satisfaction	Correlation Coefficient	.313	1.000
		Sig. (2-tailed)	.081	.
		N	32	32

Appendix 16. Change in Knowledge and General Satisfaction

Correlations

			changeknowledge	mean_satisfaction
Spearman's rho	changeknowledge	Correlation Coefficient	1.000	-.017
		Sig. (2-tailed)	.	.876
		N	87	87
	mean_satisfaction	Correlation Coefficient	-.017	1.000
		Sig. (2-tailed)	.876	.
		N	87	87

Appendix 17. Correlation: Change in Knowledge and DVD Satisfaction

Correlations			meandvdsat	changeknowledge
Spearman's rho	meandvdsat	Correlation Coefficient	1.000	-.084
		Sig. (2-tailed)	.	.648
		N	32	32
	changeknowledge	Correlation Coefficient	-.084	1.000
		Sig. (2-tailed)	.648	.
		N	32	87

Appendix 18. Modified data: excluding outliers

Between-Subjects

Factors

		N
group	DVD	39
	STND	45

Tests of Between-Subjects Effects

Dependent Variable: Totalfollowup

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	134.549 ^a	2	67.274	8.260	.001
Intercept	1947.451	1	1947.451	239.118	.000
group	.346	1	.346	.043	.837
Totalbaseline	132.058	1	132.058	16.215	.000
Error	659.689	81	8.144		
Total	35280.000	84			
Corrected Total	794.238	83			

a. R Squared = .169 (Adjusted R Squared = .149)

Appendix 19 – Normality of residuals excluding outliers

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Residual for Totalfollowup	87	82.1%	19	17.9%	106	100.0%

Descriptives

			Statistic	Std. Error
Residu	Mean		.0000	.37691
al for	95% Lower Bound		-.7493	
Totalfol	Confide Upper Bound			
lowup	nce			
	Interval		.7493	
	for			
	Mean			
	5% Trimmed Mean		.1822	
	Median		.3905	
	Variance		12.359	
	Std. Deviation		3.51555	
	Minimum		-13.60	
	Maximum		7.06	
	Range		20.66	
	Interquartile Range		3.99	
	Skewness		-1.025	.258
	Kurtosis		2.732	.511

Appendix 20 – Satisfaction Individual question data

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group2		sq1per	sq2per	sq3per	sq4per	sq5per	sq6per	sq7per	sq8per	sq9per	sq10per	sq11per	sq12per	sq13per	sq14per	sq15per	sq16per
DVD	Mean	83.659	84.448	83.670	83.078	82.894	90.360	88.815	85.869	89.884	86.585	86.548	83.473	86.597	87.753	88.527	88.181
	N	41	41	41	41	39	41	41	40	41	41	40	41	41	32	32	32
	Std. Deviation	16.1127	16.4319	17.8389	15.5106	18.2307	10.9424	12.0322	15.2348	12.1572	14.0766	16.7378	17.1522	13.8163	16.9977	16.9805	27.2489
	Median	87.619	89.048	90.476	88.095	89.524	94.762	93.810	92.619	94.762	92.381	95.476	91.429	92.381	95.238	95.476	77.371
	Std. Error of Mean	2.5164	2.5682	2.7857	2.4224	2.9193	1.7089	1.8791	2.4088	1.8986	2.1984	2.6465	2.6787	2.1577	3.0048	3.0018	4.8170
	Minimum	47.1	23.8	23.3	47.6	25.2	52.4	53.8	46.7	51.4	48.1	41.9	38.1	45.2	33.3	27.6	4.3
	Range	51.9	76.2	76.7	52.4	74.3	47.6	46.2	53.3	48.6	51.9	58.1	61.9	54.8	66.7	72.4	95.7
	Maximum	99.0	100.0	100.0	100.0	99.5	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
STND	Mean	85.481	87.070	85.145	88.478	87.598	91.118	89.689	90.441	93.079	92.433	91.087	88.392	88.519			
	N	45	46	46	46	46	46	46	41	45	46	46	45	45			
	Std. Deviation	16.8039	13.6134	16.3119	12.8148	12.1218	12.2035	14.3565	10.3304	8.5495	6.9670	11.1286	12.7587	13.7853			
	Median	89.524	90.714	90.952	91.429	90.714	95.714	95.714	94.286	95.714	94.286	94.286	93.810	93.810			
	Std. Error of Mean	2.5050	2.0072	2.4051	1.8894	1.7873	1.7993	2.1168	1.6133	1.2745	1.0272	1.6408	1.9020	2.0550			
	Minimum	12.4	24.3	46.7	29.5	50.5	33.8	25.2	68.6	63.3	71.0	41.9	51.9	51.9			
	Range	87.6	75.7	53.3	70.5	49.5	66.2	74.3	31.4	36.7	29.0	58.1	48.1	48.1			
	Maximum	100.0	100.0	100.0	100.0	100.0	100.0	99.5	100.0	100.0	100.0	100.0	100.0	100.0			
Total	Mean	84.612	85.835	84.450	85.933	85.440	90.761	89.278	88.183	91.556	89.677	88.976	86.047	87.602	87.753	88.527	88.181
	N	86	87	87	87	85	87	87	81	86	87	86	86	86	32	32	32
	Std. Deviation	16.4067	14.9763	16.9633	14.3240	15.3177	11.5656	13.2430	13.1072	10.4885	11.2330	14.1171	15.1267	13.7526	16.9977	16.9805	27.2489
	Median	89.286	90.000	90.476	90.952	90.000	95.238	94.762	94.286	95.000	93.333	94.524	92.143	92.381	95.238	95.476	77.371
	Std. Error of Mean	1.7692	1.6056	1.8187	1.5357	1.6614	1.2400	1.4198	1.4564	1.1308	1.2043	1.5223	1.6312	1.4830	3.0048	3.0018	4.8170
	Minimum	12.4	23.8	23.3	29.5	25.2	33.8	25.2	46.7	51.4	48.1	41.9	38.1	45.2	33.3	27.6	4.3
	Range	87.6	76.2	76.7	70.5	74.8	66.2	74.8	53.3	48.6	51.9	58.1	61.9	54.8	66.7	72.4	95.7
	Maximum	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0